### **TECHNOLOGY INVESTMENT AGREEMENT**

#### Between

### TEXAS PLANT-EXPRESSED VACCINE CONSORTIUM G-CON, LLC 6161 IMPERIAL LOOP BLVD SUITE 105 COLLEGE STATION, TX 77845

and

### THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY 3701 North Fairfax Drive Arlington, VA 22203-1714

### Concerning H1N1 ACCELERATION (BLUE ANGEL)

Agreement No.: HR0011-10-3-0003 ARPA Order No.: Z379/00 Effective Date of Agreement: January 21, 2010 Total Estimated Amount of the Agreement: Total Estimated Government Funding of the Agreement: Consortium Share Contribution Funds Obligated:

\$61,144,223.00 (b)(4)

Recipient Identification Numbers/Codes: (b)(4)

Authority: 10 U.S.C. § 2371

#### Line of Appropriation:

 CLIN
 ACRN
 FUNDING LINE

 0001
 AA
 9790400 1320 Z379 P9310 2525 DPAC 9 5486 S12136 62383E



This Agreement is entered into between the United States of America, hereinafter called the Government, represented by The Defense Advanced Research Projects Agency (DARPA), and Texas Plant-Expressed Vaccine Consortium (hereinafter "TPEV Consortium") pursuant to and under U.S. Federal law.

### FOR THE TEXAS PLANT-EXPRESSED FOR THE UNITED STATES OF AMERICA, VACCINE CONSORTIUM

M. Haselwood

Director of G-Con LLC

Date

THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

(b)(6) Thomas E. Lyon

Agreements Officer Contracts Management Office

110 21

Date

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## ARTICLE I: SCOPE OF THE AGREEMENT

### A. Background

1. What is the Agreement all about?

The Texas Plant-Expressed Vaccine Consortium will perform the research and development required to deliver recombinant H1N1 vaccine, expressed in hydroponic tobacco plants, at a scale of 1 kilogram (kg) of purified vaccine protein per month, that meets all Food and Drug Administration (FDA) requirements for purity, quality, and Good Manufacturing Practices (GMP) regulations.

The technical challenges in this research proposal are substantial, including the development of systems, technologies, and bioprocesses required to increase plant-based recombinant protein production by  $\sim$ 1,000 fold, and the development, implementation, and validation of additional protein purification steps to transform the current pre-clinical candidate protein to a legitimate vaccine product that meets FDA standards for commercial launch. Substantial research is also required in the areas of quality assurance, quality controls, product and contaminant assays, release criteria, standard operating procedures, etc., that are compliant with FDA standards for GMP vaccine production.

2. What is the current technological situation?

Current technology for the production of influenza vaccine relies on inoculating live influenza virus into fertilized chicken eggs. Although this process has proven relatively effective, it represents five decade-old technology and does not offer the flexibility, agility, and cost effectiveness required by the DoD and the US Government. Furthermore, there is no guarantee that it will work with influenza strains that are toxic to birds, for example, avian influenza (H5N1).

3. What makes this program a "Critical Technology" effort?

This program is a "Critical Technology" effort. In general, "critical technologies" are those that are essential for the operation or maintenance of a service or capability which could make a significant contribution to the military potential of the United States. The US military and its operations are currently at risk because there is insufficient capability to provide vaccines against pandemics caused by new strains, as well as infections caused by intentional biothreats – particularly those that have been genetically engineered. As such, warfighters' lives and health remain at risk, and critical missions could go unaccomplished as a result of unavailable human resources. The technology proposed will create a lasting capability for the US military and civilians. It will better enable the US military to be protected from infectious diseases. If successful, this effort could significantly increase flexibility and agility of vaccine development and deployment.

4. Why is the current technology not sufficient?

Currently-available technology is not sufficient to meet the Government's needs. The huge infrastructure and logistics tail associated with egg-based technology makes switching from one influenza strain to a new strain extremely time consuming and expensive. As a result, as evidenced by the current H1N1 outbreak, vaccines may not be available at the time during which they are most needed. Furthermore, the US government has expressed interest in assuring the safety and security of civilian populations in allied nations. Egg based technology does not offer the scale or cost effectiveness to do this at the level required for global safety and security.

5. Why is it necessary to develop the proof of concept and what is its impact to the military (and commercial sector)?

Development of the proof of concept is necessary and will have a substantial positive impact on the US military readiness, with significant benefits to the private sector. The production and scale-up of influenza vaccine currently relies on 1950s technology that has been in continual use since that time. While the proposed tobacco based technology is supported by strong research data, there has been no demonstration that tobacco technology for flu vaccines can be scaled up to the levels required to support the US military and US government customers. Also, there is no current approved flu vaccine produced in plants. As such, it is vital that there is a proof of concept before the technology can move into an advanced development and acquisition program.

6. What are the issues of particular importance to the issuing agency?

The Consortium will address a number of issues of particular importance to DARPA. These issues include demonstration of the ability to scale up protein production approximately 1000-fold over current scale, to produce material compatible with purity standards required for human administration, and to demonstrate the ability for all processes to comply with FDA regulatory standards.

7. What are the dual-use (military and commercial) applications?

The technology that is the subject of this Agreement has significant dual-use (military and commercial) applications. The vaccine technology developed by this project can be used to vaccinate all humans – both military and civilians, in the United States and throughout the world. Some vaccines, such as influenza, have equivalent military and civilian applications. However, the technology developed can also be applied to vaccines that have a predominant military application (for example, anthrax) or potentially those with a predominant civilian application (for example, subunit smallpox vaccine or HIV vaccines).

8. What is the market potential?

There is significant commercial market potential. If successfully scaled to the quantities proposed, and found compliant with all regulatory guidelines, and assuming positive clinical

trials demonstrating safety and protective immunity, the influenza vaccine developed here has market potential in the billion dose per year category. This is particularly relevant since the expected cost per dose will be relatively small compared to vaccines produced by current technology, thereby enabling the US government to supply vaccine to many countries which are usually "priced out" of the current global market, yet remain key US strategic partners.

9. What are the commercialization goals?

The commercialization goal of this project is to produce vaccine protein that can be used in human clinical trials. The eventual goal of the project is to produce influenza vaccine that is approved by the US FDA, and as such, becomes a commercial product.

10. If the program is successful, then what? Where do we go from here?

If this program is successful, the Texas Plant-Expressed Vaccine Consortium will perform all next manufacturing steps, and clinical trials required, in order to receive FDA approval of the vaccine. Following approval, the Consortium will maintain the vaccine capability so that it is accessible by the US government for its purposes.

11. If this collaboration is successful, what will we have accomplished?

The Collaboration will have established the first flexible, plant based vaccine (and sustained capability) to protect against infectious diseases (in particular, influenza). The vaccine capability has the potential to save millions of lives worldwide each year. Moreover, it will supply an agile capability to the DoD that will ensure the success of critical missions despite emerging infectious diseases or intentional biological threats. Once this is accomplished, we expect a plethora of new vaccines for diseases such as cancer to migrate to a plant expression system such as the one demonstrated here.

### B. Definitions

In this Agreement, the following definitions apply:

**Agreement:** The body of this Agreement and Attachments 1 through 5, which are expressly incorporated in and made a part of the Agreement.

Agreements Officer: The Government's principle point of contact for all contractual, administrative, and financial issues arising under the Agreement.

**Agreement Officer's Representative:** The Government's technical representative charged with overall responsibility for review and verification of completion of Payable Milestones and the Statement of Work, including amendments or modifications

Articles of Collaboration: The provisions of the 'Consortium Research Agreement' which define the working relationships between G-Con, LLC and The Texas A&M University System.

**Consortium:** The association of independent parties identified in Article I B managed by a Consortium Administrator established specifically to accomplish the objectives of the proposal entitled "Research, Development, Testing, and Evaluation of a Large-Scale, GMP-Compliant, Tobacco-Based Vaccine Manufacturing Capability for the US Government". The collaborative relationships are defined in a "Consortium Research Agreement" between the parties.

### Consortium Members: G-Con, LLC and The Texas A&M University System

Government: The United States of America, as represented by DARPA

**Parties:** The United States of America, hereinafter called the Government, represented by The Defense Advanced Research Projects Agency (DARPA), and Texas Plant-Expressed Vaccine Consortium (hereinafter "TPEV Consortium").

**Program:** "Accelerated Manufacture of Pharmaceuticals (AMP)" research being conducted by Texas Plant-Expressed Vaccine Consortium (hereinafter "TPEV Consortium") as described in the Attachment 1 Statement of Work.

### C. Scope

1. TPEV Consortium shall be responsible for performance of the work set forth in the Statement of Work (SOW) and Payable Milestones Plan incorporated in this Agreement as Attachments 1 and 3. The 1 kg of purified protein vaccine candidate, in bulk, will be a formal deliverable under this Agreement. Upon completion of the Agreement, the 1 kg of purified protein vaccine candidate, in bulk, will remain with the Government for disposition and use in supporting further technology/system research stimulation required prior to being ready for production or manufacturing purposes. The TPEV Consortium shall submit or otherwise provide all documentation required by Attachment 2, Report Requirements, or as otherwise stipulated in the Agreement.

2. The Government and TPEV Consortium estimate that the Statement of Work of this Agreement can only be accomplished with a TPEV Consortium aggregate resource contribution of <sup>(b)(4)</sup> The TPEV Consortium intends and, by entering into this Agreement, undertakes to cause these funds to be provided. TPEV Consortium contributions will be provided as detailed in the Funding Schedule set forth in Attachment 4. If either DARPA or the TPEV Consortium is unable to provide its respective total contribution, the other Party may reduce its project funding by a proportional amount.

No fee or cost of money is authorized under this Agreement. The TPEV Consortium shall be paid for each Payable Milestone accomplished in accordance with the Schedule of Payments and Payable Milestones set forth in Attachment 3 and the procedures of Article V.

### D. Goals / Objectives

1. The goal of this Agreement is to perform research and development in an attempt to achieve the delivery of recombinant H1N1 vaccine, expressed in hydroponic tobacco plants, at a scale of 1 kilogram (kg) of purified vaccine protein per month, that meets all FDA requirements for purity, quality, and Good Manufacturing Practices (GMP) regulations.

2. The Government will have continuous involvement with the TPEV Consortium. The Government will obtain access to Program results and certain rights in data and patents pursuant to Articles VII and VIII. DARPA and the TPEV Consortium are bound to each other by a duty of good faith in achieving the Program objectives. This Agreement reflects the collaborative document identified as "Articles of Collaboration for the "Texas Plant-Expressed Vaccine Consortium", which document binds Consortium Members.

3. This Agreement is an "other transaction" pursuant to 10 U.S.C. § 2371. The Parties agree that the principal purpose of this Agreement is for the Government to support and stimulate the TPEV Consortium to provide its best efforts in advanced research and technology development and not for the acquisition of property or services for the direct benefit or use of the Government. The Federal Acquisition Regulation (FAR) and Department of Defense FAR Supplement (DFARS) apply only as specifically referenced herein. This Agreement is not a procurement contract or grant agreement for purposes of FAR Subpart 31.205-18. This Agreement is not intended to be, nor shall it be construed as, by implication or otherwise, a partnership, a corporation, or other business organization.

## ARTICLE II: TERM

## A. Term of this Agreement

1. The Program commences upon January 21, 2010 and continues through January 31, 2011.

2. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than that specified herein, shall be given effect only to the extent defined herein and may be terminated for cause as set forth in this paragraph and paragraph B below.

## **B.** Termination Provisions

1. The Government may terminate this Agreement by written notice to the TPEV Consortium, provided that such written notice is preceded by consultation between the Parties. TPEV Consortium may request Agreement termination by giving the Government sixty (60) days written notification of their intent to do so. In the event of a termination of the Agreement, the Parties agree that disposition of Subject Inventions and Data first developed under this Agreement shall be in accordance with the provisions set forth in Articles VII, Patent Rights, and VIII, Data Rights. The Government, acting through the Agreements Officer, and TPEV Consortium will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination. The Government has no obligation to pay for any milestones to TPEV Consortium, beyond the last completed Payable Milestone, if TPEV Consortium decides to terminate. The Parties expressly agree that, under no circumstances whatsoever, shall TPEV Consortium's termination liability exceed the costs it has incurred at the time of termination or shall Government's termination liability exceed the level of funds allotted to the Agreement at the time of Agreement termination. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article VI, Disputes.

2. Subparagraph B.2 of Article V "Obligation and Payment," paragraph C of Article VI "Disputes," and Articles VII "Patent Rights," VIII "Data Rights," IX "Foreign Access to Technology," X "Export Control," XIV "Order of Precedence," XV "Execution," and XVI "Applicable Law," shall survive termination of this Agreement.

## C. Extending the Term

The Parties may extend by mutual written agreement the term of this Agreement if funding availability and research opportunities reasonably warrant. Any extension shall be formalized through modification of the Agreement by the Agreements Officer and the TPEV Consortium Administrator.

### ARTICLE III: MANAGEMENT OF THE PROJECT

### A. Consortium Members

Consortium Members, as set forth in the Articles of Collaboration of the Consortium, are:

G-Con, LLC. The Texas A&M University System

### B. Consortium Management Committee (CMC)

1. The CMC shall be comprised of at least one voting representative from each consortium member, and in accordance with the Consortium Articles of Collaboration, bind the Consortium Members. The following CMC decisions are subject to DARPA approval:

(a) Changes to the Articles of Collaboration if such changes substantially alter the relationship of the Parties as originally agreed upon when the Agreement was executed;

(b) Changes to, or elimination of, any DARPA funding allocation to any Consortium Member as technically and/or financially justified;

- (c) Technical and/or funding revisions to the Agreement; and
- (d) Admission of additional or replacement Consortium Members.

2. The CMC is responsible for establishing a schedule of regular technical meetings to be held on a quarterly basis. The CMC shall notify all Consortium Members and the DARPA Agreements Officer's Representative (AOR) of the established meeting schedule and, in the event of changes to this schedule, shall notify all Consortium Members and the DARPA Agreements Officer's Representative thirty (30) calendar days prior to the next scheduled meeting.

## C. Management and Program Structure

TPEV Consortium shall be responsible for the overall technical and program management of the Program, and technical planning and execution shall remain with TPEV Consortium insofar as it is consistent with the other provisions of this Agreement. The DARPA Agreements Officer's Representative, in consultation with the DARPA Program Manager, shall provide recommendations to program developments and technical collaboration and be responsible for the review and verification of the payable milestones.

## D. Program Management Planning Process

Program planning will consist of a Quarterly Program Plan with inputs and review from TPEV Consortium and the DARPA Agreements Officer's Representative, in consultation with the DARPA Program Manager, containing the detailed schedule of research activities and payable milestones. The Quarterly) Program Plan will consolidate adjustments in the research schedule, including mutually agreed to revisions/modification to payable milestones. TPEV Consortium will submit technical status and business status reports to DARPA in accordance with Attachment 2 in order to update DARPA on Contractor's performance under the Agreement.

1. Initial Program Plan: TPEV Consortium will follow the initial program plan that is contained in the Statement of Work (Attachment 1), and the Schedule of Payments and Payable Milestones (Attachment 3).

2. Overall Program Plan Review

(a) TPEV Consortium with DARPA Agreements Officer's Representative review, in consultation with the DARPA Program Manager, will prepare an overall Program Plan. The Program Plan will be presented and reviewed, which will be attended by TPEV Consortium management, the DARPA Agreements Officer's Representative, Senior DARPA management, as appropriate, and other DARPA program managers and personnel as appropriate.

(b) The Program Plan provides a detailed schedule of research activities, commits TPEV Consortium to use its best efforts to meet specific performance objectives, includes forecasted expenditures, and describes the Payable Milestones, consistent with the provisions of this Agreement. The Program Plan will consolidate all prior adjustments in the research schedule, including changes to payable milestones. Recommendations for modifications to the Agreement which result from the Program Review shall be made in accordance with the provisions of Article III, Section C.

### 3. Final Program Plan Review

(a) TPEV Consortium, with DARPA Agreements Officer's Representative, in consultation with the DARPA Program Manager, will prepare a Program Plan at the completion of agreement. The Final Program Plan Review will be attended by TPEV Consortium management, the DARPA Agreements Officer's Representative, Senior DARPA management, as appropriate, and other DARPA program managers and personnel as appropriate.

(b) The Final Program Plan provides a detailed schedule of research activities and describes the Payable Milestones, consistent with the provisions of this Agreement. The Final Program Plan will consolidate all prior adjustments in the research schedule, including changes to payable milestones. Recommendations for the next Phase shall be provided at this final review.

### C. Modifications

As a result of meetings or at any time during the term of the Agreement, research 1. progress or results may indicate that a change in the Statement of Work and/or the Payable Milestones, would be beneficial to Program objectives. Recommendations for modifications, including justifications to support any changes to the Statement of Work and/or the Payable Milestones, will be documented in a letter and submitted by TPEV Consortium to the DARPA Agreements Officer's Representative with a copy to the DARPA Agreements Officer. This documentation letter will detail the technical, chronological, and financial impact of the proposed modification to the Program. The DARPA Agreements Officer's Representative shall be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement Statement of Work, Schedule of Payments or Payable Milestones, or other proposed changes to the terms and conditions of this Agreement. If the Agreements Officer approves the modification, it shall come into effect only after being reduced to writing and signed by both Parties. The Government is not obligated to pay for additional or revised Payable Milestones until the Payable Milestones Schedule (Attachment 3) is formally revised by the DARPA Agreements Officer and made part of this Agreement. Other than minor modifications defined in subparagraph C.2. below or modifications that do not materially affect the Government, all modifications to this Agreement may be made only in accordance with the procedure described in this subparagraph C.1.

2. For minor or administrative Agreement modifications (e.g. changes in the paying office or appropriation data, changes to Government or TPEV Consortium personnel identified in the Agreement or other changes reasonably determined by the DARPA Agreements Officer to be strictly administrative in nature) no signature is required by TPEV Consortium.

3. The Government will be responsible for effecting all modifications to this Agreement.

### **ARTICLE IV: AGREEMENT ADMINISTRATION**

1. Unless otherwise provided in this Agreement, approvals permitted or required to be made by DARPA may be made only by the DARPA Agreements Officer. Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties.

A. Government Points of Contact.

Thomas E. Lyon DARPA Agreements Officer DARPA/CMO (HR0011) 3701 N. Fairfax Drive Arlington, VA 22203-1714 Phone: (703) 526-4107 Fax: (703) 248-8032 Email: Thomas.Lyon@darpa.mil

COL Alan J. Magill, USA DARPA Program Manager DARPA/Defense Sciences Office (DSO) (HR0011) 3701 N. Fairfax Drive Arlington, VA 22203-1714 Phone: (571) 218-4944 Fax: (571) 218-4553 Email: Alan.Magill@darpa.mil

Dr. Stephen J. Lee Agreements Officer Representative (AOR) U.S. Army Research Office (W911NF) Chemical Sciences Division 4300 South Miami Boulevard Durham, NC 27703-9142 Phone: (919) 549-4365 Fax: (919) 549-4310 Email: stephen.lee2@us.army.mil

W. Rena Wilkins
Administrative Agreements Officer (AAO)
DCMA Texas (S4402A)
600 North Pearl Street
Suite 1630
Dallas, TX 75201-2843
Phone: (214) 670-9382
Fax: (214) 670-9293
Email: Willette.Wilkins@dcma.mil

Payment Office DFAS Columbus Center (HQ0339) DFAS-CO/West Entitlement Operations P.O. Box 182381 Columbus, OH 43218-2381 Phone: 1-800-756-4571

### B. Contractor Points of Contact.

Dr. Barry Holtz TPEV Consortium Program Manager G-Con, LLC 1700 Pacific, Suite 1100 Dallas, Texas 75201 Phone: (281) 794-1436 Email: bholtz@gconbio.com

Dr. Brett P. Giroir, M.D. TPEV Consortium Program Manager The Texas A&M Research Foundation 200 Technology Way, Suite 2043 College Station, Texas 77845-3424 Phone: (979) 458-6054 Fax: (979) 458-6044 Email: Brett.Giroir@tamu.edu

David Haselwood TPEC Consortium Administrative Contact G-Con, LLC 1700 Pacific, Suite 1100 Dallas, Texas 75201 Phone: (415) 713-1263 Email: dhaselwood@gconbio.com

Each party may change its representative's named in this Article by written notification to the other party. The Government will document and effect the change as stated in item C.2 of Article III above.

2. The DCMA Administrative Agreement's Officer (AAO) is hereby delegated the responsibility to represent the Government as an Agreements Administrator for the following:

- (a) Coordinate with AOR on processing/accepting Invoices through Wide Area Workflow
- (b) Participate in program reviews and/or other equivalent meetings
- (c) Performing property administration, as required
- (d) Monitoring cost share, emphasis on year end status

- (e) Monitoring interest due the government
- (f) Tracking of total expenditures
- (g) Coordinate with the AOR and DARPA Legal Sciences Office (LSO) regarding processing of patent communications (reports, notices, etc, entered via i-edision)
- (h) Foreign access approvals
- (i) Changes (without \$\$)
- (j) Ensuring timely submission of required reports
- (k) Executing administrative closeout procedures
- (1) Terminations Equitable adjustment decisions
- (m) Duty Free Entry Assistance
- (n) Performing other administration functions as delegated by applicable cross-servicing agreements or letters of delegation.
- (o) Changes to the period of performance where there is no change to the total estimated cost.

Copies of business related documents referenced in the aforementioned are to be sent to Agreements Administrator.

# ARTICLE V: OBLIGATION AND PAYMENT

## A. Obligation

1. The Government's liability to make payments to TPEV Consortium is limited to only those funds obligated under the Agreement or by modification to the Agreement. The Government may obligate funds to the Agreement incrementally.

2. If modification becomes necessary in performance of this Agreement, pursuant to Article III, paragraph B, the DARPA Agreements Officer and TPEV Consortium Administrator shall execute a revised Schedule of Payable Milestones consistent with the then current Program Plan; however, in no event shall the Government's Estimated Funding Amount exceed that indicated herein unless the result of a mutually agreed to change in the Attachment 1 Statement of Work.

## B. Payments

1. TPEV Consortium has agreed to maintain an established accounting system that complies with Generally Accepted Accounting Principles and the requirements of this Agreement, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds. An acceptable accounting system is one in which all cash receipts and disbursements are controlled and documented properly.

2. TPEV Consortium shall document the accomplishments of each Payable Milestone by submitting or otherwise providing the Payable Milestones Report required by Attachment 2, Part B. Upon receiving the AOR's written approval of the Payable Milestone report, TPEV Consortium shall submit an invoice for the associated milestone via Wide Area Workflow as indicated at paragraph five (5) below. If deemed necessary by the Agreements Officer, the Government reserves the right to require reconciliation of Government funding with actual TPEV Consortium contributions prior to payment of Milestone Numbers 2 and 5.

3. Payments shall be made in the amounts set forth in Attachment No. 3, provided the DARPA Agreements Officer's Representative has verified the accomplishment of the Payable Milestones.

4. Limitation of Funds: In no case shall the Government's financial liability exceed the amount obligated under this Agreement.

5. Payments will be made by the cognizant Defense Agencies Financial Services office, as indicated below, within fifteen (15) calendar days of an accepted invoice in Wide Area Workflow (WAWF). Wide Area Workflow (WAWF) is a secure web-based system for electronic invoicing, receipt and acceptance. The WAWF application enables electronic form submission of invoices, government inspection, and acceptance documents in order to support DoD's goal of moving to a paperless acquisition process. Authorized DoD users are notified of pending actions by e-mail and are presented with a collection of documents required to process the contracting or financial action. It uses Public Key Infrastructure (PKI) to electronically bind the digital signature to provide non-reputable proof that the user (electronically) signed the document with the contents. Benefits include online access and full spectrum view of document status, minimized re-keying and improving data accuracy, eliminating unmatched disbursements and making all documentation required for payment easily accessible.

TPEV Consortium is required to utilize the Wide Area Workflow system when processing invoices and receiving reports under this Agreement. TPEV Consortium shall (i) ensure an Electronic Business Point of Contact is designated in Central Contractor Registration at <u>http://www.ccr.gov</u> and (ii) register to use WAWF–RA at the <u>https://wawf.eb.mil</u> site, within ten (10) calendar days after award of this Agreement. Step by Step procedures to register are available at the <u>https://wawf.eb.mil</u> site. CONSORTIUM is directed to use the "Grant/ Cooperative Agreement Invoice" format when processing invoices.

- a. For the Issue By DoDAAC enter HR0011
- b. For the Admin DoDAAC, Ship To and Service Acceptor fields, enter S4402A
- c. Leave the Inspect by DoDAAC, Ship From Code DoDAAC and LPO DoDAAC fields blank unless otherwise directed by the Agreements Officer or Administrative Agreements Officer.
- d. The following guidance is provided for invoicing processed under this Agreement through WAWF:
  - The Agreement Officer's Representative (AOR) identified at Article IV "Agreement Administration" shall continue to formally inspect and accept the deliverables/payable milestones. To the maximum extent practicable, the AOR shall review the deliverable(s)/payable milestone report(s) and either: 1) provide a written notice of rejection to TPEV Consortium which includes feedback regarding deficiencies requiring correction or 2) written notice of acceptance to

the Administrative Agreements Officer (AAO), Agreements Officer, and TPEV Consortium.

- Acceptance within the WAWF system shall be performed by the cognizant AAO upon receipt of a confirmation email, or other form of transmittal, from the AOR.
- TPEV Consortium shall send an email notice to the AOR upon submission of an invoice in WAWF (this can be done from within WAWF).
- The AAO will have WAWF forward copies of the processed acceptance to the Agreements Officer at the email address indicated at Article IV (this can be done from within WAWF).
- Payments shall be made by: DFAS Columbus Center (HQ0339) DFAS-CO/West Entitlement Operations P.O. Box 182381 Columbus, OH 43218-2381

• TPEV Consortium agrees, when entering invoices entered in WAWF to utilize the CLINs associated with each payable milestone as delineated at Attachment 3. The description of the CLIN shall include reference to the associated milestone number along with other necessary descriptive information. TPEV Consortium agrees that the Government may reject invoices not submitted in accordance with this provision.

## Note for DFAS: The OT Agreement shall be entered into the DFAS system by CLIN – Milestone association as delineated at Attachment 3. The OT Agreement is to be paid out by CLIN – Milestone association. Payments shall be made using the CLIN (MS)/ACRN association.

Financial Records and Reports: TPEV Consortium shall maintain adequate 6. records to account for Federal funds received and expended under this Agreement. TPEV Consortium's relevant financial records are subject to examination or audit on behalf of DARPA by the Government for a period not to exceed three (3) years after expiration of the term of this Agreement. The Agreements Officer or designee shall have direct access to sufficient records and information of TPEV Consortium 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. At TPEV Consortium's option, such audits or examination may be conducted by an independent certified public accounting or auditing firm designated by TPEV Consortium and agreed to by the Government (such Government concurrence shall not be unreasonably withheld) with complete reports made available to the Government upon request. The costs of any independent audit shall be paid for by TPEV Consortium and shall not be included in TPEV Consortium's cost share under the Agreement. This Agreement shall not be construed as requiring TPEV Consortium to establish systems extending beyond their current systems that are established in accordance with Generally Accepted Accounting Principles.

Upon completion or termination of this Agreement, whichever occurs earlier, TPEV Consortium shall furnish to the Agreement Officer a copy of the Final Report required by Attachment 2 of which shall include an accounting of program expenditures 7. Controller General Access to Records: To the extent that the total government payments under the Agreement exceed \$5,000,000, the Comptroller General of the United States, in its discretion, shall have access to and the right to examine records of any party to the Agreement or any entity that participates in the performance of this Agreement that directly pertain, to and involve transactions relating to, the Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any party to this Agreement or any entity that participates in the performance of the Agreement, or any subordinate element of such party or entity, that, in the year prior to the date of the Agreement, has not entered into any other contract, grant, cooperative agreement, or "other transaction" agreement that provides for audit access to its records by a government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements/contracts to the Agreement.

8. Anti-Deficiency Act Compliance: In accordance with <u>31 USC</u>, SUBTITLE II, an officer or employee of the United States Government may not make or authorize an expenditure or obligation exceeding an amount available in an appropriation or fund for the expenditure or obligation or involve the Government in a contract or obligation for the payment of money before an appropriation is made, unless authorized by law. To the extent required by this law, the Government's liability to make payments to TPEV Consortium is limited to only to those funds obligated or a modification or extension thereof to the Agreement.

### ARTICLE VI: DISPUTES

### A. General

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

### **B.** Dispute Resolution Procedures

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

2. Whenever, disagreements, claims or disputes arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall, disagreement, claim, or dispute which arose more than three (3) months prior to the notification made under subparagraph B.3 of this Article constitute the basis for relief under this Article, unless the Director of DARPA, in the interests of justice, waives this requirement.

3. Failing resolution by mutual agreement, the aggrieved Party shall document the disagreement, claim, or dispute by notifying the other Party (through the DARPA Agreements Officer as the case may be) in writing of the relevant facts, identify unresolved issues, and specify the clarification or remedy sought. Within five (5) working days after providing notice

to the other Party, the aggrieved Party may, in writing, request a joint decision by the DARPA Senior Procurement Executive and senior executive (no lower than Senior Vice President level or the equivalent) appointed by TPEV Consortium. 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 DARPA Senior Procurement Executive and the senior executive shall conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.

4. In the absence of a joint decision, upon written request to the Director of DARPA, made within thirty (30) calendar days of the expiration of the time for a decision under subparagraph B.3 above, the dispute shall be further reviewed. The Director of DARPA and a senior executive of TPEV Consortium (no lower than Senior Vice President level or the equivalent) shall jointly conduct this review. Following the review, the Director of DARPA or designee will resolve the issue(s) and notify the Parties in writing. Such resolution is not subject to further administrative review and, to the extent permitted by law, shall be final and binding.

5. Nothing in this article is intended to limit the TPEV Consortium's right to any remedy under the law. Any dispute unresolved after completing the process described in sections VI.B.1-4 above may be resolved in a court of competent jurisdiction.

## ARTICLE VII: PATENT RIGHTS

### A. Definitions

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

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

3. "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.

4. "Subject Invention" means any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

5. "License" or "license" with respect to TPEV Consortium and of its subcontractors means the right to make, have made, use, have used, lease, offer for sale, sell and/or otherwise transfer any machine, article of manufacture or composition of matter and to practice or have practiced any process.

## **B.** Allocation of Principal Rights

Unless TPEV Consortium shall have notified DARPA (in accordance with subparagraph C.2 below) that TPEV Consortium does not intend to retain title, TPEV Consortium shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article and 35 U.S.C. § 202 and 203.

With respect to any Subject Invention in which TPEV Consortium retains title, DARPA shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world.

## C. Invention Disclosure, Election of Title, and Filing of Patent Application

1. TPEV Consortium shall disclose each Subject Invention to DARPA within four (4) months after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to DARPA 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. TPEV Consortium shall also submit to DARPA an annual listing of Subject Inventions.

2. Within eight (8) months of disclosure of each Subject Invention TPEV Consortium shall elect whether to retain title to such Subject Invention and shall notify DARPA in writing of such election. However, in any case where publication, sale, or public use has initiated the one-year statutory period wherein valid patent protection can still be obtained in the United States, TPEV Consortium shall make such election and shall give written notice to DARPA not less than sixty (60) calendar days prior to the end of the statutory period.

3. TPEV Consortium 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. TPEV Consortium 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. Requests for extension of the time for disclosure, election, and filing under this paragraph, may, at the discretion of DARPA, and after considering the position of TPEV Consortium, be granted.

5. All required Subject Invention and patent-related reporting shall be accomplished, to the extent possible, using the i-Edison reporting website https://s-edison.info.nih.gov/iEdison/. TPEV Consortium shall upload Form DD 882 for subject invention certifications and subcontractor identification in connection with its annual reporting, whenever possible. To the extent any such reporting cannot be carried out by use of i -Edison, reports and communications shall be submitted to the DARPA Agreements Officer and Administrative Agreements Officer.

### D. Conditions When the Government May Obtain Title

Upon DARPA's written request, TPEV Consortium shall convey title to any Subject Invention to DARPA under any of the following conditions:

1. If TPEV Consortium fails to disclose or elects not to retain title to the Subject Invention within the times specified in paragraph C of this Article; provided, that DARPA may only request title within sixty (60) calendar days after learning of the failure of TPEV Consortium to disclose or elect within the specified times.

2. In those countries in which TPEV Consortium fails to file patent applications within the times specified in paragraph C of this Article; provided, that if TPEV Consortium has filed a patent application in a country after the times specified in paragraph C of this Article, but prior to its receipt of the written request by DARPA, TPEV Consortium shall continue to retain title in that country; or

3. In any country in which TPEV Consortium 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.

# E. Minimum Rights to TPEV Consortium and Protection of TPEV Consortium's Right to File

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

2. The TPEV Consortium domestic license may be revoked or modified by DARPA 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 TPEV Consortium has achieved practical 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 DARPA to the extent TPEV Consortium, 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, DARPA shall furnish TPEV Consortium a written notice of its intention to revoke or modify the license, and TPEV Consortium shall be allowed thirty (30) calendar days (or such other time as may be authorized by DARPA for good cause shown) after the notice to show cause why the license should not be revoked or modified.

# F. Action to Protect the Government's Interest

1. TPEV Consortium agrees to execute or to have executed and promptly deliver to DARPA all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which TPEV Consortium elects to retain title, and (ii) convey title to DARPA when requested under paragraph D of this Article and enable the Government to obtain patent protection throughout the world in that subject invention.

2. TPEV Consortium agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by TPEV Consortium each Subject Invention made under this Agreement, so that TPEV Consortium can comply with the disclosure provisions of paragraph C of this Article. TPEV Consortium shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U. S. or foreign statutory bars and to preserve the Government's Interest in the Subject Invention.

3. TPEV Consortium shall promptly notify DARPA of any decisions 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) calendar days before the expiration of the response period required by the relevant patent office.

4. TPEV Consortium shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement No. HR0011-10-3-0003 awarded by DARPA. The Government has certain rights in the invention."

# G. Lower Tier Agreements

TPEV Consortium shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work. TPEV Consortium shall ensure that the rights granted to the Government herein are also enforceable against all subcontractors and lower tiers.

### H. Reporting on Utilization of Subject Inventions

1. TPEV Consortium agrees to submit, during the term of the Agreement, an annual report on the utilization of all Subject Invention and on efforts at obtaining such utilization that is being made by TPEV Consortium 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 TPEV Consortium, and such other data and information as the agency may reasonably specify. TPEV Consortium also agrees to provide additional reports as may be requested by DARPA in connection with any march-in proceedings undertaken by DARPA in accordance with paragraph J of this Article. Consistent with 35 U.S.C. § 202(c) (5), DARPA agrees it shall not disclose such information to persons outside the Government without permission of TPEV Consortium

2. All required reporting shall be accomplished, to the extent possible, using the i-Edison reporting website <u>https://s-edison.info.nih.gov/iEdison/</u>. To the extent any such reporting cannot be carried out by use of iEdison, reports and communications shall be submitted to the Agreements Officer and Administrative Agreements Officer.

### I. Preference for American Industry

Notwithstanding any other provision of this clause, TPEV Consortium agrees that it shall not grant to any person other than TPEV Consortium Affiliates 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 DARPA upon a showing by TPEV Consortium 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.

### J. March-in Rights

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

1. Such action is necessary because TPEV Consortium 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 TPEV Consortium, assignee, or their licensees;

3. Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by TPEV Consortium, assignee, or licensees; or

4. Such action is necessary because the agreement required by paragraph (I) of this Article has not been obtained or waived or because a licensee of the exclusive right to use or sell any Subject Invention in the United States is in breach of such agreement.

The parties agree that the procedures set forth at 37 CFR 401.6 shall govern the exercise of march-in-rights.

## ARTICLE VIII: DATA RIGHTS

### A. Definitions

1. "Government Purpose Rights", as used in this Article, means rights to use, modify, reproduce, release, perform, display, or disclose Data, in whole or in part and in any manner, for Government purposes only, and to have or permit others to do so for Government purposes only.

2. "Government Purpose," as used in this Article, means any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose Data for commercial purposes or authorize others to do so.

3. "Unlimited Rights", as used in this Article, means rights to use, modify, reproduce, release, perform, display, or disclose Data, in whole or in part, in any manner and for any purposes whatsoever, and to have or permit others to do so.

4. "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 or management information.

5. "Computer Software" as used in this Article, means computer programs, source and object/compiled 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 software documentation.

6. "Computer Software Documentation" as used in this Article, 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 computer software.

7. "Data", as used in this Article, means recorded information, regardless of form or method of recording, including, but not limited to, Technical Data (to include computer software documentation), Computer Software, trade secrets, and mask works. The term does not include financial, administrative, cost, pricing or management information and does not include Subject Inventions.

8. "Background Technical Data" means any Technical Data that was not produced, generated or delivered under a previously executed Government Contract, Grant, Cooperative Agreement or Other Transaction Agreement.

9. "Foreground Technical Data" means Technical Data produced, generated, or delivered in the performance of work under this Agreement.

10. "Limited Rights", as used in this Article, means the rights to use, modify, reproduce, release, perform, display, or disclose Technical Data, in whole or in part, within the Government. The Government may not, without the written permission of the party asserting limited rights, release or disclose the Technical Data outside the Government, use the Technical Data for manufacture, or authorize the Technical Data to be used by another party, except that the Government may reproduce, release or disclose such data or authorize the use or reproduction of the Technical Data by persons outside the Government if reproduction, release, disclosure, or use is—

(i) Necessary for emergency repair and overhaul; or

(ii) A release or disclosure of Technical Data (other than detailed manufacturing or process data) to, or use of such Technical Data by, a foreign government that is in the interest of the Government and is required for evaluational or informational purposes;

(iii) Subject to a prohibition on the further reproduction, release, disclosure, or use of the Technical Data; and

(iv) The contractor or subcontractor asserting the restriction is notified of such reproduction, release, disclosure, or use.

11. "Restricted Rights", as used in this Article, means the Government's rights to:

(i) Use a computer program with one computer at one time. The program may not be accessed by more than one terminal or central processing unit or time shared unless otherwise permitted by this Agreement;

(ii) Transfer a computer program to another Government agency without the further permission of the Contractor if the transferor destroys all copies of the program and related computer software documentation in its possession and notifies the licensor of the transfer. Transferred programs remain subject to the provisions of this Article;

(iii) Make the minimum number of copies of the computer software required for safekeeping (archive), backup, or modification purposes;

(iv) Modify computer software, provided that the Government may -

(A) Use the modified software only as provided in paragraphs A (10) (i) and (iii) of this Article; and

(B) Not release or disclose the modified software except as provided in paragraphs (A) (10) (ii) of this Article.

12. "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 related Subject Invention or Inventions is or are capable of being utilized and that its or their benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

### B. Allocation of Principal Rights

1. This Agreement shall be performed with mixed Government and Contractor funding. Except as provided in B (4) and B (5) below, the Government shall receive Government Purpose Rights in all Data developed, generated, or delivered under this Agreement.

2. TPEV Consortium agrees to retain and maintain in good condition until three (3) years after expiration or termination of this Agreement, all Data necessary to achieve practical application. In the event of exercise of the Government's March-in Rights as set forth under Article VII or subparagraph B.3 of this article, TPEV Consortium agrees, upon written request from the Government, to deliver at no additional cost to the Government, all Data necessary to achieve practical application within sixty (60) calendar days from the date of the written request. The Government shall retain Unlimited Rights, as defined in paragraph A above, to this delivered Data.

3. TPEV Consortium agrees that, with respect to Data to achieve Practical Application of Subject Inventions, DARPA has the right to require TPEV Consortium to deliver all such Data to DARPA in accordance with its reasonable directions if DARPA determines that:

a. Such action is necessary because TPEV Consortium or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve Practical Application within sixty (60) calendar days from the date of the written request of the technology developed during the performance of this Agreement;

b. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by TPEV Consortium, assignee, or their licensees; or

c. Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by TPEV Consortium, assignee, or licensees.

4. With respect to all Data delivered, in the event of the Government's exercise of its right under subparagraph B (2) of this article, the Government shall receive Unlimited Rights as defined in paragraph A above.

5. With respect to any Data delivered which has been developed or generated at private expense, not including Data generated at private expense as part of the TPEV Consortium's cost share under this Agreement, the Government shall receive Limited/Restricted Rights. A list of all such Data is incorporated into the Agreement as Attachment 5.

## C. Marking of Data

Pursuant to paragraph B above, any Data delivered under this Agreement shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in Agreement HR0011-10-3-0003 between the Government and TPEV Consortium.

## D. Lower Tier Agreements

TPEV Consortium shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work. TPEV Consortium shall ensure that the rights granted to the Government herein are also enforceable against all subcontractors and lower tiers.

# ARTICLE IX: FOREIGN ACCESS TO TECHNOLOGY

This Article shall remain in effect during the term of the Agreement and for one (1) year thereafter.

## A. Definition

1. "Foreign Firm or Institution" means a firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

2. "Know-How" means all information including, but not limited to discoveries, formulas, materials, inventions, processes, ideas, approaches, concepts, techniques, methods, software, programs, documentation, procedures, firmware, hardware, technical data, specifications, devices, apparatus and machines.

3. "Technology" means discoveries, innovations, Know-How and inventions, whether patentable or not, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, maskworks, and copyrights developed under this Agreement.

## B. General

The Parties agree that research findings and technology developments arising under this Agreement may constitute a significant enhancement to the national defense, and to the economic vitality of the United States. Accordingly, access to important technology developments under this Agreement by Foreign Firms or Institutions must be carefully controlled. The controls contemplated in this Article are in addition to, and are not intended to change or supersede, the provisions of the International Traffic in Arms Regulation (22 CFR pt. 121 et seq.), the DoD Industrial Security Regulation (DoD 5220.22-R) and the Department of Commerce Export Regulation (15 CFR pt. 770 et seq.)

## C. Restrictions on Sale or Transfer of Technology to Foreign Firms or Institutions

I. In order to promote the national security interests of the United States and to effectuate the policies that underlie the regulations cited above, the procedures stated in subparagraphs C.2, C.3, and C.4 below shall apply to any transfer of Technology. For purposes of this paragraph, a transfer includes a sale of the company, and sales or licensing of Technology. Transfers do not include:

(a) sales of products or components, or

(b) licenses of software or documentation related to sales of products or components, or

(c) transfer to foreign subsidiaries of TPEV Consortium for purposes related to this Agreement, or

(d) transfer which provides access to Technology to a Foreign Firm or Institution which is an approved source of supply or source for the conduct of research under this Agreement provided that such transfer shall be limited to that necessary to allow the firm or institution to perform its approved role under this Agreement.

2. TPEV Consortium shall provide timely notice to DARPA of any proposed transfers from TPEV Consortium of Technology developed under this Agreement to Foreign Firms or Institutions. If DARPA determines that the transfer may have adverse consequences to the national security interests of the United States, TPEV Consortium, its vendors, and DARPA shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which provide substantially equivalent benefits to TPEV Consortium.

3. In any event, TPEV Consortium shall provide written notice to the DARPA Agreements Officer's Representative and Agreements Officer of any proposed transfer to a foreign firm or institution at least sixty (60) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. Within thirty (30) calendar days of receipt of TPEV Consortium's written notification, the DARPA Agreements Officer shall advise TPEV Consortium whether it consents to the proposed transfer. In cases where DARPA does not concur or sixty (60) calendar days after receipt and DARPA provides no decision, TPEV Consortium may utilize the procedures under Article VI, Disputes. No transfer shall take place until a decision is rendered.

4. In the event a transfer of Technology to Foreign Firms or Institutions which is NOT approved by DARPA takes place, TPEV Consortium shall (a) refund to DARPA funds paid for the development of the Technology and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the Government CONSORTIUM shall provide written confirmation of such licenses.

## D. Lower Tier Agreements

TPEV Consortium shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work. TPEV Consortium shall ensure that the rights granted to the Government herein are also enforceable against all subcontractors and lower tiers.

## ARTICLE X: EXPORT CONTROL

1. TPEV Consortium agrees to comply at all times with all U.S. export control laws and regulations, including, but not limited to, the International Traffic in Arms Regulations (ITAR), 22 CFR Parts 120 through 130, and the Export Administration Regulations (EAR), 15 CFR Parts 730 through 799, in the performance of this Agreement. In the absence of available license exemptions or exceptions, TPEV Consortium shall be responsible for obtaining all appropriate licenses or other approvals, including those required for exports, including deemed exports, of hardware, technical data, software, and technical assistance.

2. TPEV Consortium agrees to obtain all necessary export licenses before utilizing any foreign persons in the performance of this Agreement, including in those instances, if any, where the work is to be performed on-site at any Government installation.

3. TPEV Consortium shall be responsible for all regulatory record keeping requirements associated with the use of export licenses and license exemptions or exceptions.

4. TPEV Consortium agrees to take all necessary steps to ensure that its subcontractors comply with all applicable provisions of U.S. export control laws.

# ARTICLE XI: TITLE TO AND DISPOSITION OF PROPERTY

## A. Definitions

In this article "property" means any tangible personal property other than property actually consumed during the execution of work under this agreement.

## B. Title to Property

Title to all equipment purchased with funds available for research under this agreement shall vest with the TPEV Consortium, or one or more of its members for the benefit of the TPEV Consortium as determined from time to time by the CMC, upon acquisition without further obligation to the Government.

HR0011-10-3-0003

## ARTICLE XII: CIVIL RIGHTS ACT

This 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. TPEV Consortium has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

### **ARTICLE XIII: PUBLIC RELEASE OR DISSEMINATION OF INFORMATION**

1. There shall be no dissemination or publication, except within and between TPEV Consortium and any subcontractors, of information developed under this Agreement or contained in the reports to be furnished pursuant to this Agreement without prior written approval of the AOR. All technical reports will be given proper review by appropriate authority to determine which Distribution Statement is to be applied prior to the initial distribution of these reports by TPEV Consortium. Papers resulting from unclassified contracted fundamental research are exempt from prepublication controls and this review requirement, pursuant to DoD Instruction 5230.27 dated October 6, 1987.

2. TPEV Consortium shall submit all proposed public releases for review and approval as instructed at <u>http://www.darpa.mil/tio</u>. Public releases include press releases, specific publicity or advertisement, and publication or presentation. In addition, articles for publication or presentation will contain a statement on the title page worded substantially as follows:

"This research was, in part, funded by the U.S. Government. The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressed or implied, of the U.S. Government."

## ARTICLE XIV: ORDER OF PRECEDENCE

In the event of any inconsistency between the terms of this Agreement and language set forth in the Attachments, the inconsistency shall be resolved by giving precedence in the following order: (1) The Agreement, (2) Attachment 3 of this Agreement, (3) Attachment 1 of this Agreement, and (4) all remaining Attachments to the Agreement.

### **ARTICLE XV: 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 in writing and signed by TPEV Consortium and the DARPA Agreements Officer. This Agreement or modifications thereto may be executed in counterparts, each of which shall be deemed original, but all of which taken together shall constitute one and the same instrument.

## ARTICLE XVI: APPLICABLE LAW

United States federal law will apply to the construction, interpretation, and resolution of any disputes arising out of or in connection with this Agreement.

# ARTICLE XVII: SEVERABILITY

Invalidity or unenforceability of one or more provisions of this Agreement shall not affect any other provision of this Agreement.

Pages 31-34 denied, FOIA Exemption, 5 U.S.C. § 552(b) (4)

## **REPORT REQUIREMENTS**

Electronic copies of all reports shall be submitted within fifteen (15) days after the end of each month. All reports will be submitted to the email addresses below:

- ReportsDSO@darpa.mil Agreements Officer (AO)
- Alan.Magill@darpa.mil DARPA Program Manager
- dso\_adpm@darpa.mil DSO ADPM
- Willette.Wilkins@dcma.mil Administrative Agreements Officer (AAO)
- Stephen.Lee2@us.army.mil Agreements Officer Representative (AOR)

## A. MONTHLY REPORT

After the effective date of the Agreement and monthly thereafter throughout the term of the Agreement, TPEV Consortium shall submit or otherwise provide a monthly report. The report will have two (2) major sections.

## 1. Technical Status Report

- a. Cover Page:
  - i. Agreement number and title
  - ii. Type of report, sequence number of report, report date, and period of performance being reported
  - iii. Contractor's name, address, and telephone number
  - iv. Program Manager
  - v. Agreement Officer's Representative
- b. Section I A brief introduction covering the purpose and scope of the research effort
- c. Section II A brief description of overall progress to date plus a separate description for each task/payable milestone for which effort was expended during the report period. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved.
- d. Section III Problem Areas
  - i. A description of current problems that may impede performance along with proposed corrective action
  - ii. A description of anticipated problems that have a potential to impede progress and what corrective action is planned should the problem materialize

- e. Section IV A description of work to be performed during the next reporting period
- f. Section V Administrative Comments. Description of proposed site visits and participation in technical meetings, journal manuscripts in preparation, coordination with other organizations conducting related work, etc.
- g. Section VII Any change in staffing/team members either anticipated or unplanned. Brief description of plan to address any tasks departing staff member
- h. Section VI A Gantt Chart showing actual progress versus scheduled progress

## 2. Business Status Report

- a. Cover Page:
  - i. Agreement number and title
  - ii. Type of report, sequence number of report, report date, and period of performance being reported
  - iii. Contractor's name, address, and telephone number
  - iv. Program Manager
  - v. Agreement Officer's Representative

b. The monthly business status report shall provide summarized details of the resource status of this Agreement. The Monthly Business Status Report will provide status regarding total program expenditures, program manpower, program resourcing, subcontract status/involvement, and material/equipment purchases (to include an accounting of all pending purchases of property as required by Article XII "Title To and Disposition of Property"). Variances of actuals from planned expenditures (e.g., Initial Program Plan) for such items as manpower, materials/equipment, and subcontractors shall be discussed. Discussion of adjustment action for any major variance (greater than 10% up or down) from the Initial Program Plan shall also be provided. TPEV Consortium is strongly encouraged to utilize the American National Standards Institute/Electronic Industries Alliance Standard 748, Earned Value Management Systems (ANSI/EIS-748), or similar such methodology, as a program risk/management tool and utilize the outputs of this tool to support the Technical and Business reporting requirement herein.

## **B. PAYABLE MILESTONES REPORTS**

Starting with the first Payable Milestone, and at the completion of each Payable Milestone thereafter, TPEV Consortium shall submit a Payable Milestone Report via electronic mail to the Agreements Officer's Representative and Administrative Agreements Officer. This report shall consist, at a minimum, of an executive summary summarizing the milestone exit criteria and how all such criteria have been met, and supporting/detailed documentation describing the extent of accomplishment of Payable Milestone(s) for which TPEV Consortium is seeking Government acceptance and payment. This information shall be as required by Article III and shall be sufficient for the DARPA Agreements Officer's Representative to reasonably verify TPEV Consortium's accomplishment of the milestone in accordance with the Attachment 1 "Statement of Work" and Attachment 3 "Schedule of Payments and Payable Milestones." TPEV Consortium shall be prepared to present Payable Milestone information in the form of a briefing to the DARPA Program Manager and/or Agreement Officer's Representative. When a Payable Milestone is briefed to the Government, the Payable Milestone Report shall consist, at a minimum, of an electronic version of TPEV Consortium's briefing materials.

## C. SPECIAL TECHNICAL REPORTS/ PRESENTATION MATERIAL

As agreed to by TPEV Consortium and DARPA's Program Manager, TPEV Consortium shall submit electronically to DARPA's Program Manager, Agreements Officer's Representative and Administrative Agreements Officer any special reports on significant events such as significant target accomplishments, significant tests, experiments, or symposia. Unless otherwise instructed by the Agreements Officer's Representative, TPEV Consortium shall provide these reports/presentation materials in their own format.

# D. REPORTS, MANUSCRIPTS, AND PUBLIC RELEASE

Manuscripts, Abstracts, or papers intended for publication in any media shall be submitted to the Agreements Officer and Agreements Officer Representative, simultaneously with submission to DARPA for approval for publication. Review of such manuscripts by the AO and AOR is for comment to the Program Manager not for approval or disapproval.

TPEV Consortium shall submit all proposed public releases for review and approval as instructed at http://www.darpa.mil/tio. Public releases include press releases, specific publicity or advertisement, and publication or presentation. Allow four weeks for processing; due dates under four weeks require a justification. Unusual electronic file formats may require additional processing time. Requests can be sent either via e-mail to tio@darpa.mil or via 3701 North Fairfax Drive, Arlington VA 22203-1714, telephone (571) 218-4235. Refer to www.darpa.mil/tio for information about DARPA's public release process.

In addition, articles for publication or presentation will contain a statement on the title page worded substantially as follows:

"This research was, in part, funded by the U.S. Government. The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressed or implied, of the U.S. Government."

# E. FINAL REPORT (NOTE: The Final Report is included in the last Payable Milestone)

- TPEV Consortium shall submit or otherwise provide a Final Report making full disclosure of all major program accomplishments/developments upon completion of the Agreement or within sixty (60) calendar days of termination of this Agreement. Two (2) copies shall be submitted or otherwise provided to the Agreements Officer's Representative, one (1) copy shall be submitted or otherwise provided to the Agreements Officer, and one (1) copy shall be submitted or otherwise provided to DARPA-DSO, Attn: Assistant Director for Program Management (ADPM). Additionally, with the concurrence of the Agreement's Officer's Representative, one (1) copy shall be submitted to the Defense Technical Information Center, Attn: DTIC-BCS, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-0944 (TR@dtic.mil); and to the DARPA Library, 3701 North Fairfax Drive, Arlington, VA 22203-1714 (library@darpa.mil).
- 2. The final report shall summarize the entire research effort, citing data in the quarterly reports. The final report will provide a complete reporting of the research findings. Journal publications can be substituted for detailed descriptions of specific aspects of the research, but an original copy of each publication must be attached as an appendix and appropriately referenced in the text. All final reports must include a bibliography of all publications and meeting abstracts and a list of personnel (not salaries) receiving pay from the research effort. Although there is no page limitation for the reports, each report shall be of sufficient length to provide a thorough description of the accomplishments with respect to the approved Statement of Work. The following sections are to be part of the final report:
  - a. Section I A brief introduction covering the purpose and scope of the research effort
  - b. Section II A description of overall program progress plus a separate description for each task/payable milestone for which effort was expended during the contract period. Description shall include pertinent data and graphs in sufficient detail to explain all results achieved. Report should include negative as well as positive findings. Summarization of results to include the importance/and or implications of the completed research and any changes to future work to address the problems should be addressed. Description shall also include proposed program plan/tasks vs. actual program plan/tasks.
  - c. Section III Problem Areas
    - i. A description any problems that arose and corrective action taken
    - ii. A description of how the stated problems effected program schedule, budget, and final prototype results

- d. Section IV A Final Gantt Chart showing actual progress versus scheduled progress
- e. Section V A brief program plan for how the objectives of the next phase will be accomplished in the time period given should be discussed
- 3. The cover or title page of the final report will have the following citation:

Sponsored by Defense Advanced Research Projects Agency Defense Sciences Office (DSO) Program: Accelerated Manufacture of Pharmaceuticals (Amp) Issued by DARPA/CMO under Agreement No. HR0011-10-3-0003

The title page shall include a disclaimer worded substantially as follows:

"The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressly or implied, of the Defense Advanced Research Projects Agency of the U.S. Government."

- 4. The Final Report shall (i) be prepared in accordance with American National Standards Institute (ANSI) Standard Z39.18; (ii) include a Standard Form 298, August 1998; and (iii) be marked with an appropriate Distribution Statement.
- 5. The Final Report shall be marked with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations. The Final Report shall be marked on the front page in a conspicuous place with the following marking:

"DISTRIBUTION STATEMENT B: Distribution authorized to U.S. Government agencies only due to the inclusion of proprietary information and to prevent Premature Dissemination of potentially critical technological information. Other requests for this document shall be referred to the DARPA Technical Information Officer at tio@darpa.mil."

## F. EXECUTIVE SUMMARY

TPEV Consortium shall submit a one to two page Executive-Level Summary, along with submission of the FINAL REPORT, of the major accomplishments of the Agreement and the benefits of using the "other transactions" authority pursuant to 10 U.S.C. § 2371. This summary shall include a discussion of the actual or planned benefits of the technologies for the military and commercial sectors, as may be applicable. This summary shall be submitted electronically to the Agreements Officer, DARPA Program Manager, and Agreements Officer Representative.
## G. INTELLECTUAL PROPERTY ASSERTIONS/RESTRICTIONS REPORTING

TPEV Consortium shall identify in the final quarterly report of each phase reporting period any updates deemed necessary to the Attachment 5 Intellectual Property (IP) assertions/restrictions list based on the research results at that point in time. A final mutually agreed to IP restrictions list shall be made a part of the Final Report.

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Pages 41-44 denied, FOIA Exemption, 5 U.S.C. § 552(b) (4)

## IDENTIFICATION AND ASSERTION OF RESTRICTIONS ON THE GOVERNMENT'S USE, RELEASE, OR DISCLOSURE OF DATA

The Offeror asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following data (as defined in Article VIII - Data Rights) should be restricted:

	Technical Data or Computer Software to be Furnished with Restrictions*	Basis for Assertion**	Asserted Rights Category***	Name of Person Asserting Restrictions****
(b)(4)				

\*For technical data (other than computer software documentation) pertaining to items, components, or processes developed at private expense, identify both the deliverable technical data and each such item, component, or process. For computer software or computer software documentation identify the software or documentation.

**\*\***Generally, development at private expense, either exclusively or partially, is the only basis for asserting restrictions. For technical data, other than computer software documentation, development refers to development of the item, component, or process to which the data pertain. The Government's rights in computer software documentation generally may not be restricted. For computer software, development refers to the software. Indicate whether development was accomplished exclusively or partially at private expense. If development was not accomplished at private expense, or for computer software documentation, enter the specific basis for asserting restrictions.

**\*\*\***Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited, or government purpose rights under this or a prior contract, or specially negotiated licenses).

\*\*\*\*Corporation, individual, or other person, as appropriate.

\*\*\*\*\*Enter "none" when all data or software will be submitted without restrictions.

#### **TECHNOLOGY INVESTMENT AGREEMENT**

#### Between

## TEXAS PLANT-EXPRESSED VACCINE CONSORTIUM G-CON, LLC 6161 IMPERIAL LOOP BLVD SUITE 105 COLLEGE STATION, TX 77845

and

#### THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY 3701 North Fairfax Drive Arlington, VA 22203-1714

#### Concerning H1N1 ACCELERATION (BLUE ANGEL)

Agreement No.: HR0011-10-3-0003 Modification No.: P00001 Effective Date of Agreement: February 10, 2010 Total Estimated Amount of the Agreement: Total Estimated Government Funding of the Agreement: Consortium Share Contribution Total Funds Obligated: Funds Obligated by this Modification

\$61,144	1,223.00
(b)(4)	
\$0.00	

**Recipient Identification Numbers/Codes:** 

(b)(4	4)	

Authority: 10 U.S.C. § 2371

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by The Defense Advanced Research Projects Agency (DARPA), and Texas Plant-Expressed Vaccine Consortium (hereinafter "TPEV Consortium") pursuant to and under U.S. Federal law.

FOR THE UNITED STATES OF AMERICA, THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

(b)(6)

110

Thomas E. Lyon Agreements Officer Contracts Management Office Pursuant to Article III, E. 2, the purpose of this administrative modification is to (1) revise Article IV – Agreement Administration and (2) incorporate Attachment 2 – Revision 2 - Reporting and Meeting Requirements which Attachment supersedes all previous versions and is made part of this Agreement.

#### 1. TABLE OF CONTENTS

The following has been modified as highlighted in bold:

## ARTICLES

ARTICLE I	Scope of the Agreement
ARTICLE II	Term
ARTICLE III	Management of the Project
ARTICLE IV	Agreement Administration
ARTICLE V	Obligation and Payment
ARTICLE VI	Disputes
ARTICLE VII	Patent Rights
ARTICLE VIII	Data Rights
ARTICLE IX	Foreign Access to Technology
ARTICLE X	Export Control
ARTICLE XI	Title to and Disposition of Property
ARTICLE XII	Civil Rights Act
ARTICLE XIII	Public Release or Dissemination of Information
ARTICLE XIV	Order of Precedence
ARTICLE XV	Execution
ARTICLE XVI	Applicable Law
ARTICLE XVII	Severability

## ATTACHMENTS

ATTACHMENT 1	Statement of Work
ATTACHMENT 2 – Revision 1	Reporting and Meeting Requirements
ATTACHMENT 3	Schedule of Payments and Payable Milestones
ATTACHMENT 4	Funding Schedule
ATTACHMENT 5	Intellectual Property

2. Article IV: AGREEMENT ADMINISTRATION is DELETED in its entirety and REPLACED with the following:

## ARTICLE IV: AGREEMENT ADMINISTRATION

1. Unless otherwise provided in this Agreement, approvals permitted or required to be made by DARPA may be made only by the DARPA Agreements Officer. Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties. A. Government Points of Contact.

Thomas E. Lyon DARPA Agreements Officer DARPA/CMO (HR0011) 3701 N. Fairfax Drive Arlington, VA 22203-1714 Phone: (703) 526-4107 Fax: (703) 248-8032 Email: Thomas.Lyon@darpa.mil

COL Alan J. Magill, USA DARPA Program Manager DARPA/Defense Sciences Office (DSO) (HR0011) 3701 N. Fairfax Drive Arlington, VA 22203-1714 Phone: (571) 218-4944 Fax: (571) 218-4553 Email: Alan.Magill@darpa.mil

Dr. Stephen J. Lee Agreements Officer Representative (AOR) U.S. Army Research Office (W911NF) Chemical Sciences Division 4300 South Miami Boulevard Durham, NC 27703-9142 Phone: (919) 549-4365 Fax: (919) 549-4310 Email: stephen.lee2@us.army.mil

Sujata R. Wadhwani Administrative Agreements Officer (AAO) DCMA Texas (S4402A) 600 North Pearl Street Suite 1630 Dallas, TX 75201-2843 Phone: (214) 573-2193 Fax: (214) 670-9293 Email: <u>sujata.wadhwani@dcma.mil</u>

Payment Office DFAS Columbus Center (HQ0339) DFAS-CO/West Entitlement Operations P.O. Box 182381 Columbus, OH 43218-2381 Phone: 1-800-756-4571 B. Contractor Points of Contact.

Dr. Barry Holtz TPEV Consortium Program Manager G-Con, LLC 1700 Pacific, Suite 1100 Dallas, Texas 75201 Phone: (281) 794-1436 Email: bholtz@gconbio.com

Dr. Brett P. Giroir, M.D. TPEV Consortium Program Manager The Texas A&M Research Foundation 200 Technology Way, Suite 2043 College Station, Texas 77845-3424 Phone: (979) 458-6054 Fax: (979) 458-6044 Email: Brett.Giroir@tamu.edu

David Haselwood TPEC Consortium Administrative Contact G-Con, LLC 1700 Pacific, Suite 1100 Dallas, Texas 75201 Phone: (415) 713-1263 Email: dhaselwood@gconbio.com

Each party may change its representative's named in this Article by written notification to the other party. The Government will document and effect the change as stated in item C.2 of Article III above.

2. The DCMA Administrative Agreement's Officer (AAO) is hereby delegated the responsibility to represent the Government as an Agreements Administrator for the following:

- (a) Coordinate with AOR on processing/accepting Invoices through Wide Area Workflow
- (b) Monitoring cost share, emphasis on year end status
- (c) Tracking of total expenditures
- (d) Coordinate with the AOR and DARPA Legal Sciences Office (LSO) regarding processing of patent communications (reports, notices, etc, entered via i-edision)
- (e) Executing administrative closeout procedures

Copies of business related documents referenced in the aforementioned are to be sent to Agreements Officer.

3. Except as modified above, all provisions, terms, and conditions set forth in this Agreement remain applicable and in full force and effect.

## **REPORT REQUIREMENTS**

Electronic copies of all reports shall be submitted within fifteen (15) days after the end of each month. All reports will be submitted to the TPEV Consortium Web Portal: <u>https://extranet.darpa.mil</u>.

After logging in successfully, click on the "DSO" link to enter the area for our office and then the "G-CON" link to enter the portal. Due to limited network throughput (by design) for external access, it is recommended that large files (> 50 MB) be segmented into smaller ones.

## A. MONTHLY REPORT

After the effective date of the Agreement and monthly thereafter throughout the term of the Agreement, TPEV Consortium shall submit or otherwise provide a monthly report. The report will have two (2) major sections.

## 1. Technical Status Report

- a. Cover Page:
  - i. Agreement number and title
  - ii. Type of report, sequence number of report, report date, and period of performance being reported
  - iii. Contractor's name, address, and telephone number
  - iv. Program Manager
  - v. Agreement Officer's Representative
- b. Section I A brief introduction covering the purpose and scope of the research effort
- c. Section II A brief description of overall progress to date plus a separate description for each task/payable milestone for which effort was expended during the report period. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved.
- d. Section III Problem Areas
  - i. A description of current problems that may impede performance along with proposed corrective action
  - ii. A description of anticipated problems that have a potential to impede progress and what corrective action is planned should the problem materialize

- e. Section IV A description of work to be performed during the next reporting period
- f. Section V Administrative Comments. Description of proposed site visits and participation in technical meetings, journal manuscripts in preparation, coordination with other organizations conducting related work, etc.
- g. Section VII Any change in staffing/team members either anticipated or unplanned. Brief description of plan to address any tasks departing staff member
- h. Section VI A Gantt Chart showing actual progress versus scheduled progress

## 2. Business Status Report

- a. Cover Page:
  - i. Agreement number and title
  - ii. Type of report, sequence number of report, report date, and period of performance being reported
  - iii. Contractor's name, address, and telephone number
  - iv. Program Manager
  - v. Agreement Officer's Representative

b. The monthly business status report shall provide summarized details of the resource status of this Agreement. The Monthly Business Status Report will provide status regarding total program expenditures, program manpower, program resourcing, subcontract status/involvement, and material/equipment purchases (to include an accounting of all pending purchases of property as required by Article XII "Title To and Disposition of Property"). Variances of actuals from planned expenditures (e.g., Initial Program Plan) for such items as manpower, materials/equipment, and subcontractors shall be discussed. Discussion of adjustment action for any major variance (greater than 10% up or down) from the Initial Program Plan shall also be provided. TPEV Consortium is strongly encouraged to utilize the American National Standards Institute/Electronic Industries Alliance Standard 748, Earned Value Management Systems (ANSI/EIS-748), or similar such methodology, as a program risk/management tool and utilize the outputs of this tool to support the Technical and Business reporting requirement herein.

## **B. PAYABLE MILESTONES REPORTS**

Starting with the first Payable Milestone, and at the completion of each Payable Milestone thereafter, TPEV Consortium shall submit a Payable Milestone Report via electronic mail to the Agreements Officer's Representative and Administrative Agreements Officer. This report shall consist, at a minimum, of an executive summary summarizing the milestone exit criteria and how all such criteria have been met, and supporting/detailed documentation describing the extent of accomplishment of Payable Milestone(s) for which TPEV Consortium is seeking Government acceptance and payment. This information shall be as required by Article III and shall be

## AGREEMENT NO. HR0011-10-3-0003 ATTACHMENT NO. 2 – REVISION 1

sufficient for the DARPA Agreements Officer's Representative to reasonably verify TPEV Consortium's accomplishment of the milestone in accordance with the Attachment 1 "Statement of Work" and Attachment 3 "Schedule of Payments and Payable Milestones." TPEV Consortium shall be prepared to present Payable Milestone information in the form of a briefing to the DARPA Program Manager and/or Agreement Officer's Representative. When a Payable Milestone is briefed to the Government, the Payable Milestone Report shall consist, at a minimum, of an electronic version of TPEV Consortium's briefing materials.

## C. SPECIAL TECHNICAL REPORTS/ PRESENTATION MATERIAL

As agreed to by TPEV Consortium and DARPA's Program Manager, TPEV Consortium shall submit electronically to DARPA's Program Manager, Agreements Officer's Representative and Administrative Agreements Officer any special reports on significant events such as significant target accomplishments, significant tests, experiments, or symposia. Unless otherwise instructed by the Agreements Officer's Representative, TPEV Consortium shall provide these reports/presentation materials in their own format.

## D. REPORTS, MANUSCRIPTS, AND PUBLIC RELEASE

Manuscripts, Abstracts, or papers intended for publication in any media shall be submitted to the Agreements Officer and Agreements Officer Representative, simultaneously with submission to DARPA for approval for publication. Review of such manuscripts by the AO and AOR is for comment to the Program Manager not for approval or disapproval.

TPEV Consortium shall submit all proposed public releases for review and approval as instructed at http://www.darpa.mil/tio. Public releases include press releases, specific publicity or advertisement, and publication or presentation. Allow four weeks for processing; due dates under four weeks require a justification. Unusual electronic file formats may require additional processing time. Requests can be sent either via e-mail to tio@darpa.mil or via 3701 North Fairfax Drive, Arlington VA 22203-1714, telephone (571) 218-4235. Refer to www.darpa.mil/tio for information about DARPA's public release process.

In addition, articles for publication or presentation will contain a statement on the title page worded substantially as follows:

"This research was, in part, funded by the U.S. Government. The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressed or implied, of the U.S. Government."

# E. FINAL REPORT (NOTE: The Final Report is included in the last Payable Milestone)

- TPEV Consortium shall submit or otherwise provide a Final Report making full disclosure of all major program accomplishments/developments upon completion of the Agreement or within sixty (60) calendar days of termination of this Agreement. Two (2) copies shall be submitted or otherwise provided to the Agreements Officer's Representative, one (1) copy shall be submitted or otherwise provided to the Agreements Officer, and one (1) copy shall be submitted or otherwise provided to DARPA-DSO, Attn: Assistant Director for Program Management (ADPM). Additionally, with the concurrence of the Agreement's Officer's Representative, one (1) copy shall be submitted to the Defense Technical Information Center, Attn: DTIC-BCS, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-0944 (TR@dtic.mil); and to the DARPA Library, 3701 North Fairfax Drive, Arlington, VA 22203-1714 (library@darpa.mil).
- 2. The final report shall summarize the entire research effort, citing data in the quarterly reports. The final report will provide a complete reporting of the research findings. Journal publications can be substituted for detailed descriptions of specific aspects of the research, but an original copy of each publication must be attached as an appendix and appropriately referenced in the text. All final reports must include a bibliography of all publications and meeting abstracts and a list of personnel (not salaries) receiving pay from the research effort. Although there is no page limitation for the reports, each report shall be of sufficient length to provide a thorough description of the accomplishments with respect to the approved Statement of Work. The following sections are to be part of the final report:
  - a. Section I A brief introduction covering the purpose and scope of the research effort
  - b. Section II A description of overall program progress plus a separate description for each task/payable milestone for which effort was expended during the contract period. Description shall include pertinent data and graphs in sufficient detail to explain all results achieved. Report should include negative as well as positive findings. Summarization of results to include the importance/and or implications of the completed research and any changes to future work to address the problems should be addressed. Description shall also include proposed program plan/tasks vs. actual program plan/tasks.
  - c. Section III Problem Areas
    - i. A description any problems that arose and corrective action taken
    - ii. A description of how the stated problems effected program schedule, budget, and final prototype results

- d. Section IV A Final Gantt Chart showing actual progress versus scheduled progress
- e. Section V A brief program plan for how the objectives of the next phase will be accomplished in the time period given should be discussed
- 3. The cover or title page of the final report will have the following citation:

Sponsored by Defense Advanced Research Projects Agency Defense Sciences Office (DSO) Program: Accelerated Manufacture of Pharmaceuticals (Amp) Issued by DARPA/CMO under Agreement No. HR0011-10-3-0003

The title page shall include a disclaimer worded substantially as follows:

"The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressly or implied, of the Defense Advanced Research Projects Agency of the U.S. Government."

- 4. The Final Report shall (i) be prepared in accordance with American National Standards Institute (ANSI) Standard Z39.18; (ii) include a Standard Form 298, August 1998; and (iii) be marked with an appropriate Distribution Statement.
- 5. The Final Report shall be marked with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations. The Final Report shall be marked on the front page in a conspicuous place with the following marking:

"DISTRIBUTION STATEMENT B: Distribution authorized to U.S. Government agencies only due to the inclusion of proprietary information and to prevent Premature Dissemination of potentially critical technological information. Other requests for this document shall be referred to the DARPA Technical Information Officer at tio@darpa.mil."

## F. EXECUTIVE SUMMARY

TPEV Consortium shall submit a one to two page Executive-Level Summary, along with submission of the FINAL REPORT, of the major accomplishments of the Agreement and the benefits of using the "other transactions" authority pursuant to 10 U.S.C. § 2371. This summary shall include a discussion of the actual or planned benefits of the technologies for the military and commercial sectors, as may be applicable. This summary shall be submitted electronically to the Agreements Officer, DARPA Program Manager, and Agreements Officer Representative.

## AGREEMENT NO. HR0011-10-3-0003 ATTACHMENT NO. 2 – REVISION 1

## G. INTELLECTUAL PROPERTY ASSERTIONS/RESTRICTIONS REPORTING

TPEV Consortium shall identify in the final quarterly report of each phase reporting period any updates deemed necessary to the Attachment 5 Intellectual Property (IP) assertions/restrictions list based on the research results at that point in time. A final mutually agreed to IP restrictions list shall be made a part of the Final Report.

#### **MODIFICATION P00002 TO THE TECHNOLOGY INVESTMENT AGREEMENT**

Between

TEXAS PLANT-EXPRESSED VACCINE CONSORTIUM G-CON, LLC 6161 IMPERIAL LOOP BLVD SUITE 105 COLLEGE STATION, TX 77845

and

THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY 3701 North Fairfax Drive Arlington, VA 22203-1714

Concerning H1N1 ACCELERATION (BLUE ANGEL)

Agreement No.: HR0011-10-3-0003 Modification No.: P00002 Effective Date of Agreement: September 20, 2010 Total Estimated Amount of the Agreement: Total Estimated Government Funding of the Agreement: Consortium Share Contribution Total Funds Obligated: Funds Obligated by this Modification



**Recipient Identification Numbers/Codes:** 

Authority: 10 U.S.C. § 2371

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by The Defense Advanced Research Projects Agency (DARPA), and Texas Plant-Expressed Vaccine Consortium (hereinafter "TPEV Consortium") pursuant to and under U.S. Federal law.

(b)(4)

FOR THE TEXAS PLANT-EXPRESSED

David M. Haselwood

David M. Haselwood Director of G-Con LLC

FOR THE UNITED STATES OF AMERICA, THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

(b)(6)

Michael S. Mutty Agreements Officer Contracts Management Office

9/17/2010 Date

Pursuant to Article III, E. 2, the purpose of this modification is to (1) increase the Consortium cost share by \$4,342,000 from \$21,146,160 to \$25,488,160, thereby increasing the total amount of the Agreement to \$65,486,223; (2) extend the Term of the Agreement by an additional four (4) months; (3) revise Article IV – Agreement Administration and (4) incorporate Attachment 1 – Revision 1 – Statement of Work, Attachment 3 - Revision 1 - Schedule of Payments and Payable Milestones, and Attachment 4 – Revision 1 – Funding Schedule which Attachments supersedes all previous versions and is made part of this Agreement; and (5) other administrative changes to the Agreement.

#### 1. TABLE OF CONTENTS

The following has been modified as highlighted in bold:

#### ARTICLES

ARTICLE I	Scope of the Agreement
<b>ARTICLE II</b>	Term
ARTICLE III	Management of the Project
ARTICLE IV	Agreement Administration
ARTICLE V	Obligation and Payment
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ARTICLE XIII	Public Release or Dissemination of Information
ARTICLE XIV	Order of Precedence
ARTICLE XV	Execution
ARTICLE XVI	Applicable Law
ARTICLE XVII	Severability

#### ATTACHMENTS

ATTACHMENT 1 – Revision 1 ATTACHMENT 2 – Revision 1 ATTACHMENT 3 – Revision 1 ATTACHMENT 4 – Revision 1 ATTACHMENT 5 Statement of Work Reporting and Meeting Requirements Schedule of Payments and Payable Milestones Funding Schedule Intellectual Property

#### 2. ARTICLE I: SCOPE OF THE AGREEMENT

The following has been modified as highlighted in bold:

C. Scope

2. The Government and TPEV Consortium estimate that the Statement of Work of this Agreement can only be accomplished with a TPEV Consortium aggregate resource contribution of The TPEV Consortium intends and, by entering into this Agreement, undertakes to cause these funds to be provided. TPEV Consortium contributions will be provided as detailed in the Funding Schedule set forth in Attachment 4. If either DARPA or the TPEV Consortium is unable to provide its respective total contribution, the other Party may reduce its project funding by a proportional amount.

#### 3. ARTICLE II: TERM

The following has been modified as highlighted in bold:

- A. Term of this Agreement
  - 1. The Program commences upon January 21, 2010 and continues through April 30, 2011.
- 4. Article IV: AGREEMENT ADMINISTRATION is DELETED in its entirety and REPLACED with the following:

## ARTICLE IV: AGREEMENT ADMINISTRATION

1. Unless otherwise provided in this Agreement, approvals permitted or required to be made by DARPA may be made only by the DARPA Agreements Officer. Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties.

A. Government Points of Contact.

Michael S. Mutty DARPA Agreements Officer DARPA/CMO (HR0011) 3701 N. Fairfax Drive Arlington, VA 22203-1714 Phone: (571) 218-4588 Fax: (703) 741-7806 Email: Michael.Mutty@darpa.mil

COL Alan J. Magill, USA DARPA Program Manager DARPA/Defense Sciences Office (DSO) (HR0011) 3701 N. Fairfax Drive Arlington, VA 22203-1714 Phone: (571) 218-4944 Fax: (571) 218-4553 Email: Alan.Magill@darpa.mil

Dr. Stephen J. Lee Agreements Officer Representative (AOR) U.S. Army Research Office (W911NF) Chemical Sciences Division 4300 South Miami Boulevard Durham, NC 27703-9142 Phone: (919) 549-4365 Fax: (919) 549-4310 Email: stephen.lee2@us.army.mil Sujata R. Wadhwani Administrative Agreements Officer (AAO) DCMA Texas (S4402A) 600 North Pearl Street Suite 1630 Dallas, TX 75201-2843 Phone: (214) 573-2193 Fax: (214) 670-9293 Email: <u>sujata.wadhwani@dcma.mil</u>

Payment Office DFAS Columbus Center (HQ0339) DFAS-CO/West Entitlement Operations P.O. Box 182381 Columbus, OH 43218-2381 Phone: 1-800-756-4571

#### B. Contractor Points of Contact.

Dr. Barry Holtz TPEV Consortium Program Manager G-Con, LLC 1700 Pacific, Suite 1100 Dallas, Texas 75201 Phone: (281) 794-1436 Email: bholtz@gconbio.com

Dr. Brett P. Giroir, M.D. TPEV Consortium Program Manager The Texas A&M Research Foundation 200 Technology Way, Suite 2043 College Station, Texas 77845-3424 Phone: (979) 458-6054 Fax: (979) 458-6054 Email: Brett.Giroir@tamu.edu

David Haselwood TPEC Consortium Administrative Contact G-Con, LLC 1700 Pacific, Suite 1100 Dallas, Texas 75201 Phone: (415) 713-1263 Email: dhaselwood@gconbio.com

Each party may change its representative's named in this Article by written notification to the other party. The Government will document and effect the change as stated in item C.2 of Article III above.

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2. The DCMA Administrative Agreement's Officer (AAO) is hereby delegated the responsibility to represent the Government as an Agreements Administrator for the following:

- (a) Coordinate with AOR on processing/accepting Invoices through Wide Area Workflow
- (b) Monitoring cost share, emphasis on year end status
- (c) Tracking of total expenditures
- (d) Coordinate with the AOR and DARPA Legal Sciences Office (LSO) regarding processing of patent communications (reports, notices, etc, entered via i-edision)
- (e) Executing administrative closeout procedures

Copies of business related documents referenced in the aforementioned are to be sent to Agreements Officer.

5. Attachment 1 – Statement of Work is hereby deleted in its entirety and replaced with Attachment 1 – Revision 1 – Statement of Work.

6. Attachment 3 – Schedule of Payments and Payable Milestones is hereby deleted in its entirety and replaced with Attachment 3 – Revision 1 - Schedule of Payments and Payable Milestones

7. Attachment 4 – Funding Schedule is hereby deleted in its entirety and replaced with Attachment 4 – Revision 1- Funding Schedule

Except as modified above, all provisions, terms, and conditions set forth in this Agreement remain applicable and in full force and effect.

Pages 61-70 denied, FOIA Exemption, 5 U.S.C. § 552(b) (4)

#### **MODIFICATION P00003 TO THE TECHNOLOGY INVESTMENT AGREEMENT**

Between

#### TEXAS PLANT-EXPRESSED VACCINE CONSORTIUM G-CON, LLC

6161 IMPERIAL LOOP BLVD SUITE 105 COLLEGE STATION, TX 77845

and

#### THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

3701 North Fairfax Drive Arlington, VA 22203-1714

#### Concerning H1N1 ACCELERATION (BLUE ANGEL)

Agreement No.: HR0011-10-3-0003 Modification No.: P00003 Effective Date of Modification: February 15, 2011 Total Estimated Amount of the Agreement: Total Estimated Government Funding of the Agreement: Consortium Share Contribution Total Funds Obligated: Funds Obligated by this Modification

65,486,2	23.00
b)(4)	
0.00	
50.00	

**Recipient Identification Numbers/Codes:** 

(b)(4)	

Authority: 10 U.S.C. § 2371

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by The Defense Advanced Research Projects Agency (DARPA), and Texas Plant-Expressed Vaccine Consortium (hereinafter "TPEV Consortium") pursuant to and under U.S. Federal law.

FOR THE TEXAS PLANT-EXPRESSED VACCINE CONSORTIUM

FOR THE UNITED STATES OF AMERICA, THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

David M. Haselwood

Director of G-Con LLC

Michael S. Mutty Agreements Officer Contracts Management Office

2/14/2011

Date

1

#### HR0011-10-3-0003 Modification P00003

Pursuant to Article III, E. 2, the purpose of this modification is to (1) extend the Term of the Agreement by an additional two (2) months; and (2) incorporate Attachment 3 - Revision 2 - Schedule of Payments and Payable Milestones which Attachment supersedes all previous versions and is made part of this Agreement.

#### 1. TABLE OF CONTENTS

The following has been modified as highlighted in bold:

#### **ATTACHMENTS**

ATTACHMENT 1 – Revision 1 ATTACHMENT 2 – Revision 1 ATTACHMENT 3 – Revision 2 ATTACHMENT 4 – Revision 1 ATTACHMENT 5 Statement of Work Reporting and Meeting Requirements Schedule of Payments and Payable Milestones Funding Schedule Intellectual Property

#### 2. ARTICLE II: TERM

The following has been modified as highlighted in bold:

- A. Term of this Agreement
  - 1. The Program commences upon January 21, 2010 and continues through July 31, 2011.

3. Attachment 3 – Revision 1 - Schedule of Payments and Payable Milestones is hereby deleted in its entirety and replaced with Attachment 3 – Revision 2 - Schedule of Payments and Payable Milestones

Except as modified above, all provisions, terms, and conditions set forth in this Agreement remain applicable and in full force and effect.

Pages 73-75 denied, FOIA Exemption, 5 U.S.C. § 552(b) (4)

#### **MODIFICATION P00004 TO THE TECHNOLOGY INVESTMENT AGREEMENT**

Between

#### **TEXAS PLANT-EXPRESSED VACCINE CONSORTIUM** G-CON, LLC 6161 IMPERIAL LOOP BLVD

SUITE 105 COLLEGE STATION, TX 77845

and

## THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

3701 North Fairfax Drive Arlington, VA 22203-1714

#### Concerning H1N1 ACCELERATION (BLUE ANGEL)

Agreement No.: HR0011-10-3-0003 Modification No.: P00004 Effective Date of Modification: July 19, 2011 Total Estimated Amount of the Agreement: Total Estimated Government Funding of the Agreement: Consortium Share Contribution Total Funds Obligated: Funds Obligated by this Modification

\$65,486,22 (b)(4)	23.00
\$0.00	

**Recipient Identification Numbers/Codes:** 

(b)(4)		

Authority: 10 U.S.C. § 2371

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by The Defense Advanced Research Projects Agency (DARPA), and Texas Plant-Expressed Vaccine Consortium (hereinafter "TPEV Consortium") pursuant to and under U.S. Federal law.

FOR THE TEXAS PLANT-EXPRESSED VACCINE CONSORTIUM

David M. Haselwood Director of G-Con LLC

FOR THE UNITED STATES OF AMERICA, THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

Michael S. Mutty Agreements Officer Contracts Management Office

Date

1

Pursuant to Article III, E. 2, the purpose of this modification is to (1) extend the Term for an additional Four (4) months with no change to the estimated amount of the Agreement; and (2) incorporate the mutually agreed to changes to Attachment 3 - Revision 3 - Schedule of Payments and Payable Milestones Accordingly, make the following changes to the Agreement:

#### 1. TABLE OF CONTENTS

The following has been modified as highlighted in bold:

#### ATTACHMENTS

ATTACHMENT 1 – Revision 1 ATTACHMENT 2 – Revision 1 ATTACHMENT 3 – Revision 3 ATTACHMENT 4 – Revision 1 ATTACHMENT 5 Statement of Work Reporting and Meeting Requirements Schedule of Payments and Payable Milestones Funding Schedule Intellectual Property

#### 2. ARTICLE II: TERM

The following has been modified as highlighted in bold:

- A. Term of this Agreement
  - 1. The Program commences upon January 21, 2010 and continues through November 30, 2011.

3. Attachment 3 – Revision 2 - Schedule of Payments and Payable Milestones is hereby deleted in its entirety and replaced with Attachment 3 – Revision 3 - Schedule of Payments and Payable Milestones

Except as modified above, all provisions, terms, and conditions set forth in this Agreement remain applicable and in full force and effect.

Pages 79-80 denied, FOIA Exemption, 5 U.S.C. § 552(b) (4)

#### MODIFICATION P00005 TO THE TECHNOLOGY INVESTMENT AGREEMENT

Between

TEXAS PLANT-EXPRESSED VACCINE CONSORTIUM G-CON, LLC 6161 IMPERIAL LOOP BLVD SUITE 105 COLLEGE STATION, TX 77845

and

THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY 3701 North Fairfax Drive Arlington, VA 22203-1714

Concerning H1N1 ACCELERATION (BLUE ANGEL)

Agreement No.: HR0011-10-3-0003 Modification No.: P00005 Effective Date of Modification: October 31, 2011 Total Estimated Amount of the Agreement: Total Estimated Government Funding of the Agreement: Consortium Share Contribution Total Funds Obligated: Funds Obligated by this Modification

<u>\$65,48</u> (b)(4)	<u>6,223.00</u>
\$0.00	

**Recipient Identification Numbers/Codes:** 

(b)(4)			
	-	 -	-

Authority: 10 U.S.C. § 2371

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by The Defense Advanced Research Projects Agency (DARPA), and Texas Plant-Expressed Vaccine Consortium (hereinafter "TPEV Consortium") pursuant to and under U.S. Federal law.

FOR THE TEXAS PLANT-EXPRESSED VACCINE CONSORTIUM

David M. Haselwood Director of G-Con LLC

FOR THE UNITED STATES OF AMERICA, THE DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

Michael S. Mutty Agreements Officer Contracts Management Office

11/01/2011

Date

1

Pursuant to Article III, E. 2, the purpose of this modification is to (1) extend the Term for an additional Three (3) months with no change to the estimated amount of the Agreement; and (2) incorporate the mutually agreed to changes to Attachment 3 - Revision 4 - Schedule of Payments and Payable Milestones. Accordingly, make the following changes to the Agreement:

#### 1. TABLE OF CONTENTS

The following has been modified as highlighted in bold:

#### ATTACHMENTS

ATTACHMENT 1 – Revision 1 ATTACHMENT 2 – Revision 1 ATTACHMENT 3 – Revision 4 ATTACHMENT 4 – Revision 1 ATTACHMENT 5 Statement of Work Reporting and Meeting Requirements Schedule of Payments and Payable Milestones Funding Schedule Intellectual Property

#### 2. ARTICLE II: TERM

The following has been modified as highlighted in bold:

- A. Term of this Agreement
  - 1. The Program commences upon January 21, 2010 and continues through January 31, 2012.

3. Attachment 3 – Revision 3 - Schedule of Payments and Payable Milestones is hereby deleted in its entirety and replaced with Attachment 3 – Revision 4 - Schedule of Payments and Payable Milestones

Except as modified above, all provisions, terms, and conditions set forth in this Agreement remain applicable and in full force and effect.

(b)(4)