OTHER TRANSACTION AGREEMENT

BETWEEN

POTENTIAL PERFORMER

AND

THE ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH (ARPA-H)

CONCERNING

PROPOSE EFFORT

Agreement No.: 1AYSAX00000X

Total Amount of the Agreement: $ X,XXX,XXX [*Base + Exercised Options*]
Base: $ X,XXX,XXX
Option 1: $ X,XXX,XXX
Option 2: $ X,XXX,XXX

Authority: 42 U.S.C. 290(c)(g)(1)(D)

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by The Advanced Research Projects Agency for Health (ARPA-H), and *POTENTIAL PERFORMER*. pursuant to and under United States Federal law.

FOR *POTENTIAL PERFORMER*	FOR THE GOVERNMENT ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH
X	X
(Name, Title)	(Jennifer M. Mack, Agreement Officer)

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ARTICLES

ATTACHMENTS

ARTICLE 1: SCOPE OF THE AGREEMENT

A. Background

THIS PARAGRAPH(S) DESCRIBES THE VISION OF THE PROGRAM AND SHOULD ADDRESS THE FOLLOWING:

- *THE PURPOSE OF THE AGREEMENT/PROJECT*
- *THE CURRENT TECHNOLOGICAL SITUATION (CURRENT STATE OF THE ART)*
- *WHAT MAKES THE PROGRAM/PROJECT A "CRITICAL TECHNOLOGY" EFFORT*
- *WHY THE CURRENT TECHNOLOGY IS NOT SUFFICIENT (FOR THE US HEALTH CARE MARKET)*
- *WHAT IS THE PERCEIVED BENEFIT OF HAVING THE GOVERNMENT AS A PARTNER IN THIS PROGRAM AND/OR PROJECT? ADDRESSING THE ISSUES OF PARTICULAR IMPORTANCE TO BOTH INDUSTRY AND ARPA-H*
- *WHAT THE MARKET POTENTIAL IS IF SUCCESSFUL*
- *WHAT THE TECHNOLOGY TRANSITION GOALS ARE FOR ARPA-H, AND WHAT THE COMMERCIALIZATION GOALS ARE FOR THE PERFORMER*
- *WHAT WILL WE HAVE ACCOMPLISHED IF THIS COLLABORATION IS SUCCESSFUL*

[APPROXIMATELY 1 PAGE SHOULD BE SUFFICIENT TO DISSCUSS/ADDRESS THE ABOVE TOPICS. A FEW SENTENCES SHOULD SUFFICE TO ADDRESS EACH BULLET. PRESENT IN INTEGRATED/CONCISE NARRATIVE FORMAT]

B. Definitions

In this Agreement, the following definitions apply:

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

Agreements Officer (AO): The Government's principle point of contact for all contractual, administrative and financial issues arising under the Agreement. Notwithstanding any other provision of this Agreement, the Agreements Officer is the only individual within the Government authorized to redirect the effort or in any way amend or modify any of the terms of this Agreement. Legal notices, including notices of disputes, proposed technology transfers under Article 7, invention disclosures, patent and patent application notices, and any notices relating to any allegation or claim relating to intellectual property infringement shall be referred to the Agreements Officer.

Agreements Officer's Representative (AOR): The Government's technical representative charged with overall responsibility for review and verification of completion of Payable Milestones and the Technical Description Document, including amendments or modifications thereto, as set forth herein. The Agreements Officer's Representative is not otherwise authorized to make any representations or commitments of any kind on behalf of the Agreements Officer or the Government. The AOR does not have the authority to alter the Performer's obligations or to change the specifications of the Agreement.

Covered Foreign Country: The People's Republic of China.

Covered Government Support Contractor: A contractor under a contract, the primary purpose of which is to furnish independent and impartial advice or technical assistance directly to the Government in support of the Government's management and oversight of a program or effort.

Covered telecommunications equipment or services:

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) Video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a Covered Foreign Country.

Critical technology:

(1) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(2) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Data: Recorded information, regardless of form or method of recording, which includes, but is not limited to, copyrightable material; unpatentable computer software, including programs, code, documentation, and databases; trademarks; and maskworks. The term does not include financial, administrative, cost, pricing, or management information and does not include Subject Inventions, as defined in this Article.

Effective Date: The date of the last signature hereon.

Foreign Firm or Institution: 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.

Government: The United States of America, as represented by ARPA-H.

Government Purpose: Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national 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.

Government Purpose Rights: The right to use, modify, reproduce, perform, display, release, or disclose, 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.

Information System: A discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

Intellectual Property: The intangible creations of the human mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. Such creations may be protected in the law as patents, copyrights, trademarks, or trade secrets."

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

Know-How: 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.

Limited Rights: The right to use, modify, reproduce, release, perform, display, or disclose, in whole or in part, within the Government. The Government may not, without the written permission of the Performer, release or disclose outside the Government, use for manufacture, or authorize use by another party. The Performer agrees that the Government may release or disclose to a covered Government support contractor in performance of its covered Government support contract.

Made: When used in relation to any invention means the conception or first actual reduction to practice of such invention.

Party: Includes the Government (represented by ARPA-H), or the Performer, or both.

Performer: *POTENTIAL PERFORMER*

Practical Application: 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.

Program: Research and development being conducted by the Performer, as set forth in Article 1(A).

Property: Any tangible personal property other than property actually consumed during the execution of work under this Agreement. For purposes of this article, "property" does not include the deliverable prototype which is the (*PROTOTYPE NAME*).

Subject Invention: Any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

Technology: 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.

Unlimited Rights: The right to use, modify, reproduce, perform, display, release, or disclose, in whole or in part, in any manner and for any purposes whatsoever, and to have or permit others to do so as well.

C. Scope

1. This Agreement is an "other transaction" pursuant to 42 U.S.C. 290(c)(g)(1)(D). The principal purpose of this Agreement is to perform a coordinated research and development program ("Program") designed to develop BLANK. This research shall be carried out in accordance with Attachment 1, Task Description Document (TDD). The Performer shall submit or otherwise provide all documentation required by Attachment 2, Report Requirements.

2. The Performer shall be paid a fixed amount for each milestone accomplished in accordance with the Schedule of Milestones and Payments set forth in Attachment 3 and the procedures of Article 5.

D. Goals / Objectives

1. The goal(s) of this Agreement are outlined in Attachment 1 and Attachment 3.

2. The Government will have continuous involvement with the Performer. The Government will obtain access to Program results and rights in patents and data pursuant to Articles 7. ARPA-H and the Performer are bound to each other by a duty of good faith in achieving the Program objectives.

ARTICLE 2: TERM

A. Term of this Agreement

The Program commences upon the Execution Date and continues for thirty-six (36) months. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified herein, shall be given effect, notwithstanding this Article.

B. Termination Provisions

Subject to a reasonable determination that the program will not produce beneficial results, either Party may terminate this Agreement by written notice to the other Party, provided that such written notice is preceded by consultation between the Parties. In the event of a termination of the Agreement, it is agreed that disposition of Data developed under this Agreement, shall be in accordance with the provisions set forth in Article 7. The Government and the Performer will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article 6. The Government has no obligation to pay the Performer beyond the last completed and paid milestone if the Performer decides to terminate. Should the Government terminate the Agreement for reasons other than breach of the Agreement by the Performer, the Performer shall be entitled to a pro-rata payment for partial completion of a funded milestone as determined by a good faith assessment of such partially completed milestone which shall be formalized through modification of the Agreement per Article 3.

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 ("AO") and the Performer Administrator.

(i) The term of this Agreement may be extended prior to the end of each phase per Attachment 3; provided that the Government gives the Performer a preliminary written notice of its intent to extend at least thirty (30) days before the Agreement expires. The preliminary notice does not commit the Government to an extension.

(ii) If this option is exercised, the extended Agreement shall be considered to include this Article.

(iii) The total duration of this Agreement, including the exercise of any options under this Article, shall not exceed the total Agreement term set forth in Attachment 3.

ARTICLE 3: MANAGEMENT OF THE PROJECT

A. Management and Program Structure

The Performer shall be responsible for the overall technical and program management, technical planning and execution of the Program. The Agreements Officer's Representative ("AOR"), in consultation with the ARPA-H Program Manager ("PM"), shall provide recommendations to Program developments and technical collaboration and be responsible for the review and verification of the completed milestone

B. Program Management Planning Process

Program planning will consist of a Program Plan with inputs and reviews from the Performer and ARPA-H management, containing a detailed schedule of research activities and milestones.

The Performer, with ARPA-H PM participation and review, will prepare an overall Program Plan for the active phase that will be delivered to the Government within 10 business days prior to the kickoff meeting. The Program Plan may be presented and reviewed initially at the kickoff meeting, and subsequent program review meetings, at the discretion of the ARPA-H PM.

The Program Plan provides a detailed schedule of research activities, commits the Performer to meet specific performance objectives and describes the program/technical milestones. The Program Plan will consolidate all prior adjustments in the research schedule, including revisions/modifications to prospective milestones. Recommendations for changes and technical revisions or modifications to the Agreement which result from the kickoff meeting or subsequent program review meetings, shall be made in accordance with the provisions of Article 3, Section C.

C. Modifications

1. As a result of meetings, annual reviews, or at any time during the term of the Agreement, research progress or results may indicate that a change in the TDD would be beneficial to project objectives. Recommendations for modifications, including justifications to support any changes to the TDD and prospective milestones, will be documented and submitted by the Performer to the ARPA-H PM and AOR with a copy to the AO. This documentation will detail the technical, chronological, and financial impact of the proposed modification to the research project. The Government is not obligated to pay for additional or revised future milestones until Attachment 3 to this Agreement is formally amended via bilateral modification.

2. The ARPA-H AOR/PM shall be responsible for the review and verification of any recommendations to modify the TDD, prospective milestones, or other proposed changes to the terms and conditions of this Agreement.

3. For minor or administrative Agreement modifications (e.g., incremental funding, changes in the paying office or appropriation data, changes to Government or the Performer's personnel identified in the Agreement, etc.) no signature is required by the Performer.

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

ARTICLE 4: AGREEMENT ADMINISTRATION

Unless otherwise provided in this Agreement, approvals permitted or required to be made by ARPA-H may be made only by the ARPA-H AO. Administrative and contractual matters under this Agreement shall be referred to the following representatives of the Parties:

A. Government Points of Contact:

Agreements Officer (AO):
NAME
Org: ARPA-H; Business Innovation Division
Email:

ARPA-H Program Manager (PM):
NAME
Org: ARPA-H; BLANK Office
Email:

Agreements Officer's Representative (AOR):
NAME
Org: ARPA-H; BLANK Office
Email:

B. Performer Points of Contact

Performer's Administrative/Contracting:
[INSERT NAME]
[INSERT ORGANIZATIN/OFFICE]
[INSERT PHONE NUMBER]
[INSERT EMAIL ADDRESS]

Performer's Program Investigator (PI):
[INSERT NAME]
[INSERT ORGANIZATIN/OFFICE]
[INSERT PHONE NUMBER]
[INSERT EMAIL ADDRESS]

ARTICLE 5: OBLIGATION AND PAYMENT

The Government's liability to make payments to the Performer is limited to only those funds obligated under this Agreement or by modification to the Agreement. This Agreement may be subject to BLANK funding, as indicated in Attachment 3, which is presently made available for performance under this Agreement.

B. Payments

1. The Parties agree that fixed payments will be made for the completion of milestones. These payments reflect value received by the Government toward the accomplishment of the research goals of this Agreement.

2. The Performer shall document the accomplishments of each milestone by submitting or otherwise providing the Milestone Reports required by Attachment 2. After written verification of the accomplishment of the milestone by the AOR, the Performer will submit their invoice to the AO for payment approval through the Payment Management Services (PMS), as detailed in Article 5(B)(3).

3. The Performer is required to utilize the PMS when processing invoices under this Agreement. PMS is a centralized payment and cash management system. Payments are made by PMS, operated by PSC, in accordance with Department of the Treasury and OMB requirements.

The Performer shall (i) maintain an active registration for 'All Awards' in System for Award Management (SAM) throughout the life of the award, (ii) ensure an Electronic Business Point of Contact is designated in System for Award Management at http://www.sam.gov, and (iii) register to use PMS, within ten (10) calendar days after award of this Agreement. PMS guidance can be found here: https://pms.psc.gov/training/grant-recipient-training.html .

The following guidance is provided for invoicing processed under this Agreement:

- The AOR identified in Article 4, "Agreement Administration" shall continue to formally inspect and accept the deliverables/ milestones. The AOR shall review the deliverable(s)/ milestone report(s) within fourteen (14) calendar days after submission of the applicable report and either: 1) provide a written notice of rejection to the Performer which includes feedback regarding deficiencies requiring correction, or 2) written notice of acceptance to the Performer, ARPA-H PM and AO. The basis for rejection of a payable milestone shall be that such payable milestone, the accomplishment of which is captured in the associated Payable Milestone Report, fails to meet the acceptance criteria stipulated in Attachment 3 of the agreement. If the Government objects to the acceptance of a Payable Milestone (to include one or more of the deliverables thereunder), the Government will work with Performer so that the Performer has reasonable opportunities to cure/redeliver the associated Payable Milestone/Report. After written verification of the accomplishment by the AOR, the Performer will receive payment via PMS for amounts set forth in Attachment 3.

a. Payee Information: As identified at the System for Award Management.

- Cage Code: BLANK
- UEI: BLANK

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

C. Financial Records and Reports

Upon completion or termination of this Agreement, whichever occurs earlier, the Performer shall furnish a copy of the Final Report required by Attachment 2. As indicated in Attachment 2, no financial reporting is required.

D. Records Retention and Government Access

The Comptroller General of the United States, or any of their duly authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of the Performer that are pertinent solely to the Performer's technical performance under this Agreement, in order to make examinations, excerpts, transcripts and copies of such documents. This right also includes timely and reasonable access to the Performer's personnel for the purpose of interview and discussion related to such records. Such access shall be performed during business hours on business days upon written notice and shall be subject to the security requirements of the audited party to the extent such security requirements do not conflict with the rights of access otherwise granted by this paragraph. The rights of access in this paragraph shall last as long as records are retained. The rights of access in this paragraph do not extend to the Performer's financial records.

[This subparagraph will be deleted/marked "Reserved" during negotiations if the proposer confirms in writing to the Agreements Officer that it does not currently provide the Government access to records per the terms and conditions of another contractual instrument.]

E. Audits and Accounting System Compliance

This is a fixed-support Other Transaction utilizing a milestone payment method that is not subject to audit by the United States Government and the Performer is not required to include this Program in any governmental audits. Additionally, as such, this Agreement establishes no requirements pertaining to use of the Performer's accounting or timekeeping system(s).

F. Accounting and Appropriation Data

See Attachment 3.

ARTICLE 6: 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 ARPA-H and the Performer concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, may be raised only under this Article, which describes the applicable administrative review process. Completion of this process forecloses any further administrative review and must be pursued prior to any other dispute resolution process.

2. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. Unless waived by the Director of ARPA-H, no dispute, disagreement or misunderstanding which arose more than three

(3) months from when the Party knew or should have known the basis of the action prior to the notification made under Article 6 (B)(3), which constitutes the basis for relief under this Article.

3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the ARPA-H AO or the Performer's Administrator, 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 ARPA-H Head of Contracting Authority (HCA), and senior executive no lower than [*INSERT A LEVEL OF EXECUTIVE FAR ENOUGH REMOVED FROM THE PROGRAM TO MAINTAIN A GREATER LEVEL OF IMPARTIALITY*] level appointed by the Performer. 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. ARPA HCA 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 Deputy Director of ARPA-H, made within thirty (30) calendar days of the expiration of the time for a decision under Article 6 (B)(3), the dispute shall be further reviewed. The Deputy Director of ARPA-H may elect to conduct this review personally or through a designee or jointly with a senior executive no lower than [*INSERT A LEVEL OF EXECUTIVE FAR ENOUGH REMOVED FROM THE PROGRAM AND ABOVE THE PERSON IDENTIFIED AT SUBPARAGRAPH 3 TO MAINTAIN A GREATER LEVEL OF IMPARTIALITY*] level appointed by the Performer. Following the review, the Deputy Director of ARPA-H or designee will resolve the issue(s) and notify the Parties in writing. To the extent permitted by law, such resolution shall be final and binding, except that if not satisfied with the results of completing the administrative review process, either party may pursue any right and remedy in a court of competent jurisdiction.

C. Limitation of Damages

Claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of ARPA-H funding obligated as of the time the dispute arises. In no event shall ARPA-H be liable for claims for consequential, punitive, special, and incidental damages, claims for lost profits, or other indirect damages.

ARTICLE 7: INTELLECTUAL PROPERTY RIGHTS

A. Patent Rights

1. Allocation of Principal Rights – Performer

(a) Unless the Performer shall have notified ARPA-H in writing that the Performer does not intend to retain title, the Performer shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article.

(b) For each Subject Invention to which the Government obtains title, the Performer shall retain a nonexclusive, royalty-free license throughout the world to said Subject Invention. This license extends to the Performer's domestic subsidiaries and affiliates, including Canada, if any, and includes the right to grant license of the same scope to the extent that the Performer was legally obligated to do so at the time the Agreement was awarded. Said license is transferable only with the approval of the ARPA-H

AO, except when transferred to the successor of that part of the business to which the Subject Invention pertains. ARPA-H approval for license transfer shall not be unreasonably withheld.

2. Allocation of Principal Rights – ARPA-H

(a) With respect to any Subject Invention in which the Performer retains title, ARPA-H shall retain a nonexclusive, nontransferable, irrevocable, paid-up Government Purpose license in the Subject Invention throughout the world, regardless of the protection method chosen.

(b) Upon ARPA-H's written request, the Performer shall convey title to any Subject Invention to ARPA-H under the following conditions. ARPA-H may only request title within sixty (60) calendar days after learning of the Performer's actions.

1. The Performer fails to disclose a Subject Invention prior to the completion of the Agreement, or
2. The Performer elects not to retain title to a Subject Invention.

(c) Regarding Article 7(A)(2)(b)(1), ARPA-H shall not make any such request in an arbitrary or capricious manner and/or not in abuse of its discretion, and all such requests shall be subject to Article 6, "Disputes," in this Agreement.

3. Invention Disclosure, Election of Title, and Election of Protection Method

(a) The Performer shall disclose each Subject Invention to ARPA-H within four (4) months after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure shall be made to the ARPA-H AO and shall be in the form of a written report sufficiently complete in technical detail. The report shall identify the Agreement number, the circumstances under which the invention was made, the identity of the inventor, and any publication, sale or public use of the invention.

(b) If the Performer determines that it does not intend to retain title to any Subject Invention, the Performer shall notify ARPA-H in writing no more than sixty (60) calendar days prior to the end of the one (1) year statutory United States patent protection period.

(c) If the Performer chooses to retain title to any Subject Invention, the Performer shall inform the ARPA-H AO of its corporate determination how to best protect any Subject Invention. The Performer shall choose one of the following two options to protect any Subject Invention.

1. Protection of the Subject Invention through the patent process

a. If the Performer chooses to file a patent application in the United States or other countries or forums throughout the world, the Performer shall notify ARPA-H of this decision, the dates on which the patent applications was filed and where it was filed.
b. The Performer shall notify ARPA-H of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding 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.
c. The Performer shall include, within the specification of any United States patent application and any patent issued covering a subjection invention, the following statement:

"This invention was made with U.S. Government support under Agreement No. (INSERT AWARD NUMBER) awarded by the Advanced Research Projects Agency for Health. The U.S. Government has rights in the invention."

2. Protection of the Subject Invention as a trade secret

a. If the Performer chooses not to patent the Subject Invention but instead protect it as a trade secret, the Performer shall notify the ARPA-H AO of this decision in writing within eight (8) months of the Performer's disclosure of the invention to ARPA-H.

ARPA-H may, at its discretion, approve requests for an extension of time for electing to protect a Subject Invention as a trade secret, and such a request will not be unreasonably withheld. Such requests may be made within or after the eight-month deadline.

b. In that notification, the Performer shall state the applicable law that will govern protection of the trade secret as well as any special protection methods or actions that the Performer will take to ensure secrecy.

c. If the Government discloses a Subject Invention which is protected as a trade secret to a Covered Government Support Contractor, the Government will ensure trade secrets remain protected under an obligation of confidentiality with respect to such Covered Government Support Contractors. In order to ensure necessary confidentiality is maintained, Performer will negotiate in good faith with the goal of entering into a non-use and-disclosure agreement with a third party at the Government's request to cover information developed under this Agreement that discloses a Subject Invention that is maintained as a trade secret and is to be used by the third party solely for Government Purposes. Performer will disclose such information to the third party within fifteen (15) calendar days of entering into a non-use and -disclosure agreement.

4. Administrative Actions

(a) At the completion of the Agreement, the Performer shall submit a comprehensive listing of all Subject Inventions disclosed under Article 7(A)(1)-(3) during the course of the Agreement and the current status of each.

1. All required reporting shall be done, to the extent possible, using the i-Edison reporting website: https://nist.gov/iedison. To the extent that the reporting cannot be accomplished by use of i-Edison, any required documentation will be submitted to the ARPA-H AO.

(b) The Performer agrees to execute or have executed and promptly deliver to ARPA-H all instruments necessary to:

1. Establish or confirm the rights the Government has throughout the world in any Subject Invention to which the Performer elects to retain title, and
2. Convey title to ARPA-H when requested under Article 7(A)(2)(b) and to enable the Government to obtain patent protection throughout the world in the Subject Invention.

(c) The Performer agrees to instruct and educate its employees of the importance of disclosing inventions promptly to corporate personnel responsible for the administration of patent matters to permit sufficient time to satisfy its notification responsibilities under this Agreement.

5. Exceptional Circumstances

(a) The Parties recognize that the Government is making a significant investment in the Subject Inventions under this Agreement. To protect the Government's interests, the Parties agree to the following in the event that the Performer goes out of business or otherwise exits the [INSERT DESCRIPTION] industry; or otherwise makes the Subject Inventions unavailable to the Government:

1. Upon ARPA-H's request and an adequate showing of need, the Performer, assignee or exclusive licensee will provide a non-exclusive license to a responsible applicant or applicants, under terms that are reasonable under the circumstances, and
2. If the Performer, assignee or exclusive licensee refuses a reasonable request from the Government, ARPA-H has the right to grant such a license itself if ARPA-H makes a reasonable determination that such action is necessary to alleviate societal health or safety needs or national security needs, which are not reasonably satisfied, by the Performer, assignee, or exclusive licensees.

B. Data Rights

1. Allocation of Principal Rights

(a) The Parties agree that in consideration for Government funding, the Performer intends to utilize in commercial business the Intellectual Property developed under this Agreement.

(b) With respect to Data delivered pursuant to Attachments 1 through 3 of this Agreement, the Government shall receive rights as stipulated below and in Attachment 3 except as noted in the following two subparagraphs:

Data Rights Identifier*	Data Rights Type	Term
GPR	Government Purpose Rights	In perpetuity
ULR	Unlimited Rights	In perpetuity
LR	Limited Rights	In perpetuity

[*WHICH OF THE ABOVE DATA RIGHTS TYPES APPLY WILL BE NEGOTIATED BASED ON THE FINAL MILESTONE PLAN – ANY RIGHTS NOT USED WILL BE DELETED FROM THE DEFINITIONS SECTION IN ARTICLE I AS WELL AS THE MARKINGS SECTION BELOW*]

(c) With respect to the following Data deliverables, the Government shall receive BLANK Rights (this may be modified by the AO depending on the rights asserted by the performer):

1. Technical Status Reports
2. Milestone Reports
3. Final Report(s)

(d) The Government may require delivery of Data developed or generated under this Agreement, if not previously delivered, within two (2) years after completion or termination of this Agreement. Any request for delivery of data will be made in writing with at least sixty (60) days' notice. Upon the Government making such a request, the parties will negotiate in good faith the applicable Data

rights for the requested Data prior to delivery, and the Government will reimburse the Performer for reasonably incurred costs for gathering and delivery of the Data.

2. Exceptional Circumstances

(a) Notwithstanding any other provision of this Section, in the event the Government chooses to exercise its rights under Article 7(A)(5), the Performer agrees to deliver at no additional cost to the Government all Data necessary to achieve practical application of a specified Subject Invention. The Government shall retain Unlimited Rights, as defined in Article 1, Definitions of this Agreement, to this delivered Data.

(b) To facilitate any future requests and deliveries, the Performer agrees to retain and maintain in good condition for three (3) years after completion or termination of this Agreement all Data necessary to achieve practical application of any Subject Invention as defined in Article 1 of this Agreement.

(c) The Government is required to execute this exercise of rights in writing and the Performer agrees to deliver the Data within sixty (60) calendar days from the date of the written request. The Performer may request an extension of this time period by making a written justification to the Government and such a request will not be unreasonably withheld.

3. Marking of Data

(a) Any Data delivered under this Agreement shall be marked with the following legends, as applicable:

"GOVERNMENT PURPOSE RIGHTS
Agreement Number: 1AYSAX00000X
Contractor Name: [*INSERT PERFORMER NAME*]

In accordance with Article 7, as applicable, contained in the above identified Agreement, the Government has the right to: (a) use, modify, reproduce, perform, display, release, or disclose, 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. Government Purposes includes any activity in which the United States Government is a party, including cooperative agreements with international or multi-national 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. Any reproduction of this Data or portions thereof marked with this legend must also reproduce the markings."

"LIMITED RIGHTS
Prime Agreement No.: 1AYSAX00000X
Performer Name: [*INSERT PERFORMER NAME*]
In accordance with Article 7, as applicable, contained in the above identified Agreement, the Government has the right to use, modify, reproduce, release, perform, display, or disclose, in whole or in part, within the Government. The Government may not, without the written permission of the Performer, release or disclose outside the Government, use for manufacture, or authorize use by another party. The Government may release to a covered Government support contractor in performance of its Government support contract. Any reproduction of this Data or portions thereof marked with this legend must also reproduce the markings."

"UNLIMITED RIGHTS
Agreement Number: 1AYSAX00000X
Contractor Name: [*INSERT PERFORMER NAME*]
In accordance with Article 7, as applicable, contained in the above identified Agreement, the Government has the right to use, modify, reproduce, perform, display, release, or disclose, in whole or in part, in any manner and for any purposes whatsoever, and to have or permit other to do so as well."

C. Lower Tier Agreements

The Performer shall include this Article, suitably modified, in all subcontracts or lower tier agreements, for experimental, developmental, or research work.

ARTICLE 8: FOREIGN ACCESS TO TECHNOLOGY

This Article shall remain in effect during the term of the Agreement and for BLANK (X) years thereafter.

A. General

The Parties agree that research findings and technology developments arising under this Agreement may constitute a significant enhancement to the security and to the economic vitality of the United States. Accordingly, access to important intellectual property developments under this Agreement by foreign entities 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 Regulations (ITAR)(22 CFR Parts 120-130) and the Department of Commerce's Export Administration Regulations (EAR)(15 CFR Parts 730-774) regarding export-controlled items, or the Performer's responsibility to comply with all applicable laws and regulations regarding export-controlled items and the handling of classified information exists independent of, and is not established or limited by, the information provided by this article. The Performer shall consult with the Department of State regarding any questions relating to compliance with ITAR and shall consult with the Department of Commerce regarding any questions relating to compliance with EAR.

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

1. In order to best capitalize on the financial investment by the Government in the program and promote the national security interests of the United States, ARPA-H reserves the right to be notified and discuss options with the Performer before Performer's transfer Intellectual Property developed or generated under this Agreement to a Foreign Firm or Institution. It is not ARPA-H's intention to unduly restrict the Performer's ability to promote and sell its products and services in the global market. ARPA-H's intention is to protect the Government's investment and ability to fully utilize its licenses to the intellectual property in the future. For purposes of this Article, a transfer includes the sale of the Performer and all its assets, or the sale or exclusive licensing of the Intellectual Property developed or generated under this Agreement. A transfer does not include:

(a) Sales of products or components, and non-exclusive licenses of intellectual property related to sales of products or components (i.e., software, documentation), in the course of normal business practice; or
(b) Licenses of software or documentation related to open-source software; or
(c) Transfers to foreign subsidiaries of the Performer for purposes related to the performance of 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. Notwithstanding any provisions of this Article, the Performer agrees to transfer Intellectual Property developed or generated under this Agreement to United States firms and institutions or to a firm or institution that agree to substantially manufacture products embodying the Intellectual Property or produced through the use of the Intellectual Property in the United States. If the Performer is unsuccessful in finding a firm or institution that is capable of manufacturing substantially in the United States, the Performer may request a waiver to this requirement from ARPA-H. In doing so, the Performer shall illustrate to ARPA-H the Performer has made all reasonable efforts to find a firm or institution capable of manufacture substantially in the United States.

3. In any event the Performer requests a waiver under Article 8(B)(2), the Performer shall provide written notice to the AOR and the ARPA-H AO 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 the Performer's written notification, the ARPA-H AO shall advise the Performer whether it consents to the proposed transfer. In cases where ARPA-H does not concur or sixty (60) calendar days after receipt and ARPA-H provides no decision, the Performer may utilize the procedures under Article 6, Disputes. No transfer shall take place until a decision is rendered.

4. In the event the Performer transfers the intellectual property developed or generated under this Agreement without ARPA-H's written assent (a) the Performer shall refund to ARPA-H the full amount of Government funds paid under the Agreement for the development of the intellectual property, 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 intellectual property, regardless of form or protection method, throughout the world for Government Purposes. Upon request of the Government, the Performer shall provide written confirmation of such licenses.

C. Lower Tier Agreements

The Performer 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.

ARTICLE 9: TITLE TO AND DISPOSITION OF PROPERTY

A. Title to Property

The Performer will acquire property with an acquisition value greater than $5,000 under this Agreement, as set forth in Attachment 5, which is necessary to further the research and development goals of this Program and is not for the direct benefit of the Government. Title to this property shall vest in the Performer upon acquisition. Title to any other items of property acquired under this Agreement with an acquisition value of $5,000 or less shall vest in the Performer upon acquisition with no further obligation of the Parties unless otherwise determined by the AO. Should any other item of property with an acquisition value greater than $5,000 be required, the Performer shall obtain prior written approval of the AO. Title to this property shall also vest in the Performer upon acquisition. The Performer shall be responsible for the maintenance, repair, protection, and preservation of all property at its own expense.

B. Disposition of Property

At the completion of the term of this Agreement, items of property set forth in this Agreement or any other items of property with an acquisition value greater than $5,000 will be dispositioned in one of the following manners, depending on the property in question, and a recommendation from the PM.

1. Purchased by the Performer at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale being returned to ARPA-H; or

2. Transferred to a Government research facility with title and ownership being transferred to the Government; or

3. Donated to a mutually agreed University or technical learning center for research purposes; or

4. Any other ARPA-H approved disposition procedure.

ARTICLE 10: PUBLIC RELEASE OR DISSEMINATION OF INFORMATION

There are no publication restrictions. The Performer and any subcontractors/subrecipients may publish and make public communications and presentations make regarding the results of their work under this Agreement without any prior written approval. Additionally, articles for publication or presentation will contain a statement on the title page worded substantially as follows:

> "This research was funded, in part, 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."

Or

1. Except with regard to subcontractors, team members, or other program participants, the Performer agrees to restrict dissemination or publication of information developed or generated under this Agreement without prior written approval by ARPA-H.

2. The following information or documents will not be subject to the requirements of Paragraph 1 of this Article.

(a) Unclassified information or documents used in the patent process, copyright approval process, or trademark approval process,

(b) Papers prepared in response to academic requirements which are not intended for public release outside the academic institution, or

(c) Information or documents related to program activities that have been determined to be fundamental research.

3. The Performer shall submit any proposed public releases that reference the United States Government, or ARPA-H in any form or references the program name or the names of any government staff for review and approval to the ARPA-H Division of Communication (DOC). Public releases may include press releases, specific publicity or advertisement, and publication or presentation, but exclude those relating to open sourcing or licensing, sales or other commercial exploitation of products, services,

or technologies. In addition, articles for publication or presentation that mention ARPA-H in any form, or the name of the program will contain a statement on the title page worded substantially as follows:

> "This research was funded, in part, 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 11: 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. § 2000d) relating to nondiscrimination in Federally assisted programs. The Performer has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

ARTICLE 12: SECURITY

The Performer, and any applicable subcontractor, will be required to follow all applicable HHS Policy for Information Technology Procurements (i.e., Security and Privacy), National Institute of Standards and Technology (NIST) Special Publications (e.g., 800 series) and are bound by the Federal Information Modernization Act (FISMA) if and when accessing, creating, maintain a federal information system or otherwise accessing Federal Data in the performance of the Project. Additionally, the *Federal Information Processing Standards Publication 201-3 Personal Identify Verification of Federal Employees and Contractors* will apply to any Performer personnel that requires logical or physical access to ARPA-H.

ARTICLE 13: KEY PERSONNEL

A. The Performer shall notify the AO in writing prior to making any change in key personnel. The following individuals are designated as key personnel for the purposes of this Agreement:

Name	**Role/Title**
[*INSERT NAME*]	[*PRINCIPAL INVESTIGATOR*]
[*INSERT NAME*]	[*INSERT ROLE/TITLE*]
[*INSERT NAME*]	[*INSERT ROLE/TITLE*]

B. When replacing any of the personnel identified above, the Performer must demonstrate that the qualifications of the prospective personnel are acceptable to the Government as reasonably determined by the PM. Substitution of key personnel shall be documented by modification to the Agreement made in accordance with the procedures outlined in Article 3, Section C.

ARTICLE 14: EXECUTION

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations, and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written modification thereto per Article 3(C). This Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.

ARTICLE 15: FORCE MAJEURE

The Performer shall not be liable for delays or non-performance hereunder if such delay or non-performance is from causes beyond the control and without the fault or negligence of the Performer or its subcontractors, and is due, directly, to fire or other casualty; act of God; strike or labor dispute; war or other violence, or to acts of the Government in either its sovereign or contractual capacity.

ARTICLE 16: SURVIVAL

The Articles covering Definitions, Payments, Records Retention and Government Access, Disputes, Limitation of Damages, Intellectual Property Rights, Foreign Access To Intellectual Property, Public Release Or Dissemination Of Information, Applicable Law, Order of Precedence, Public Release or Dissemination of Information, and Survival shall survive the completion, termination, or expiration of this Agreement.

ARTICLE 17: PROHIBITION ON CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT

A. Prohibition

In accordance with Public Law 115-232, Section 889 (b), the Performer is prohibited from obligating or expending funds received by the Government under this Agreement to:

1. Procure or obtain;
2. Extend or renew a contract to procure or obtain; or
3. Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses Covered Telecommunications Equipment or Services as a substantial component of any system, or as Critical Technology as part of any system.

B. Lower Tier Agreements

The Performer shall include this Article, suitably modified, in all subcontracts or lower tier agreements.

ARTICLE 18: GOVERNMENT FURNISHED PROPERTY/INFORMATION

Government furnished property/information will not be provided to the Performer in performance of this Agreement.

Or

The Government Furnished Property/Information identified in Attachment X will be provided to the Performer as stipulated therein in performance of this Agreement.

ARTICLE 19: SPECIAL TERMS AND CONDITIONS

A. Salary Rate Limitation

1. The Performer shall not use program funds (under this Agreement) to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated. For the purposes of the salary rate limitation, "Direct salary," "salary", and "institutional base salary", have the same meaning and are collectively referred to as "direct

salary." An individual's direct salary is the annual compensation that the Performer pays for an individual's direct effort (costs) under the Agreement. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Performer. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

NOTE: The salary rate limitation does not restrict the salary that an organization may pay an individual working under the Agreement, it merely limits the portion of that salary that may be paid with Federal funds.

2. The salary rate limitation also applies to individuals under subawards.

B. Reporting Matters Involving Fraud, Waste and Abuse

The HHS Office of the Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS [1-800-447-8477]) for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. Information also may be submitted online at https://tips.oig.hhs.gov/ or by mail to U.S. Department of Health and Human Services, Office of the Inspector General, Attn: OIG HOTLINE OPERATIONS, P.O. Box 23489 Washington DC 20026. Such reports are treated as sensitive material and submitters may decline to give their names if they choose to remain anonymous. For additional information, see: https://oig.hhs.gov/fraud/report-fraud/.

C. Prohibition on Contractor Involvement with Terrorist Activities

The Performer acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Performer to ensure compliance with these Executive Orders and Laws.

Lower Tier Agreements

The Performer shall include this paragraph, suitably modified, in all subcontracts or lower tier agreements.

D. Research Misconduct

Title 42 CFR 93, PHS Policies on Research Misconduct, Subpart C, "Responsibilities of Institutions" specifies awardee responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity and take all reasonable and practical steps to foster research integrity. Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The HHS Office of Research Integrity (ORI) has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities.

E. Registration with the Select Agent Program for Work Involving the Possession, Use, and/or Transfer of Select Biological Agents or Toxins

1. Work involving select biological agents or toxins shall not be conducted under this Agreement until the Performer and any affected subawards are granted a certificate of registration or are authorized to work with the applicable select agents.

2. For prime or subawards to domestic institutions who possess, use, and/or transfer Select Agents under this Agreement, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

3. For prime or subawards to foreign institutions who possess, use, and/or transfer Select Agents under this Agreement, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Performer must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the AO, the Performer shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Performer must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the OTA.

4. Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

F. Research Involving Recombinant or Synthetic Nucleic Acid Molecules

The Performer shall ensure that all work involving the use of recombinant DNA will be in compliance with the "National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules."

ARTICLE 20: HUMAN SUBJECT RESEARCH

A. Protection of Human Subjects

1. The Performer agrees that any engagement in human subjects involved in research under this Agreement shall occur in accordance with 45 CFR Part 46 and the Performer's current Federalwide Assurance (FWA) on file with the HHS Office for Human Research Protections (OHRP). Similarly, Performer agrees that any human subjects research under this Agreement shall occur in accordance with any applicable law, regulation, or rule enforced by the U.S. Food and Drug Administration including, but not limited to 21 CFR 50, 56, 312, and 812. The Performer further agrees to provide certification to the AOR that an overseeing Institutional Review Board has reviewed and approved, as required by applicable law and regulation, any human subjects research occurring under this Agreement prior to the engagement in such research.

2. The Performer shall retain full responsibility for the performance of all work and services involving human subjects research under this Agreement in accordance with the terms of this award.

3. If at any time during the performance of this Agreement, the AO determines that the Performer is not in compliance with any of the requirements and/or standards stated in paragraphs (1) and (2) above, the AO may immediately suspend, in whole or in part, work and further payments under this Agreement until the Performer corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Performer fails to complete corrective action within the period of time designated in the AO's written notice of suspension, the AO may terminate this Agreement in a whole or in part.

B. Human Materials

1. The acquisition and supply of all human specimen material (including fetal material) used under this Agreement shall be obtained by Performer in full compliance with applicable Federal, State and Local laws and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

2. The Performer shall provide written documentation that all human materials obtained as a result of engagement in non-exempt research involving human subjects conducted under this Agreement or by subawards identified under this Agreement, were obtained after acceptance and approval by the Office for Human Research Protections (OHRP) of the engaged entity's FWA. This restriction applies to all collaborating sites, whether domestic or foreign, and compliance must be ensured by the Performer.

3. The Performer shall provide to the AO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials, were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/ Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

C. Research Involving Human Fetal Tissue

All research involving human fetal tissue shall be conducted in accordance with 42 U.S.C. 289g-2 and 45 CFR 46.206. Additionally, all research involving the transplantation of human fetal tissue shall be conducted in accordance with 42 U.S.C. 289g-1, and for such research the Performer shall make available, for audit by the Secretary, HHS, the physician statements, and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Performer.

D. Human Embryo Research and Cloning

HHS funds may not be used to support human embryo research. In addition, no funding may be used for cloning human beings.

E. Needle Exchange

The Performer shall not use Agreement funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE 21: ANIMAL SUBJECT RESEARCH (ASR)

A. Care of Live Vertebrate Animals

1. Before undertaking performance of any OT involving animal related activities, the Performer shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.27. The Performer shall furnish evidence of the registration to the Agreement Officer.

2. The Performer shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 through 2.13, or from a source that is exempt from licensing under those sections.

3. The Performer agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this OT will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the National Academy of Sciences Institute of Laboratory Animal Resources, the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1- 4). In case of conflict between standards, the more stringent standard shall be used.

4. If at any time during performance of this Agreement, the AO's determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Performer is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the AO's may immediately suspend, in whole or in part, work and further payments under this Agreement until the Performer corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Performer fails to complete corrective action within the period of time designated in the AO's written notice of suspension, the AO's may, in consultation with OLAW, terminate this Agreement in whole or in part, and the Performer's name may be removed from the list of those organizations with approved PHS Animal Welfare Assurances.

   Note: The Performer may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. Information concerning this program may be obtained by contacting your regional office below or the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

B. Animal Welfare

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the Animal Welfare Act (7 U.S.C. 2131 et. seq.), the U.S. Government Principles and the Guide for the Care and Use of Laboratory Animals.

C. Protection of Personnel Who Work with Nonhuman Primates

All Performer personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates."

D. Information on Compliance with Animal Care Requirements

Registration with the U.S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.). The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW). An essential requirement of the PHS Policy is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service. If the Performer does not have an assurance and will be utilizing a subaward to perform the animal work, then the Performer and subaward must have an Inter-Institutional Assurance in place to allow the Performer to utilize the assurance of the subaward to meet the HHS requirements for assurance. The request for this negotiation of this assurance must be submitted to OLAW by NIH on behalf of the Performer.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals and that they comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy. The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given" the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies.

E. Approval of Required Assurance by Law

Funds shall not be expended by the Performer for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Performer under this award unless a satisfactory assurance of compliance with the Animal Welfare Act, including 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the U.S. Government Principles and the Guide for the Care and Use of Laboratory Animals is submitted by Performer 30 days prior to commencing research involving live vertebrate animals and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve Jive vertebrate animals) may be conducted by individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28.

ARTICLE 22: ASSOCIATE CONTRACTOR AGREEMENT (ACA)

(a) It is recognized that the success of the BLANK research effort depends in part upon the open exchange of information between the various Associate Contractors involved in the effort. This is intended to ensure that there will be appropriate coordination and integration of work by the Associate Contractors to achieve complete compatibility and to prevent unnecessary duplication of effort. By executing this Agreement, the Contractor assumes the responsibilities of an Associate Contractor. For the purpose of this ACA, the term Contractor includes subsidiaries, affiliates, and organizations under the control of the contractor (e.g. subcontractors).

(b) Work under this contract may involve access to proprietary or confidential data from an Associate Contractor. To the extent that such data is received by the Contractor from any Associate Contractor for the performance of this contract, the Contractor hereby agrees that any proprietary information received shall remain the property of the Associate Contractor and shall be used solely for the purpose of the BLANK research effort. Only that information which is received from another contractor in writing, and which is clearly identified as proprietary or confidential shall be protected in accordance with this provision. The obligation to retain such information in confidence will be satisfied if the Contractor receiving such information utilizes the same controls as it employs to avoid disclosure, publication, or dissemination of its own proprietary information. The receiving Contractor agrees to hold such information in confidence as provided herein so long as such information is of a proprietary/confidential or limited rights nature.

(c) The Contractor hereby agrees to closely cooperate as an Associate Contractor with the other Associate Contractors on this research effort. This involves as a minimum:

(1) maintenance of a close liaison and working relationship;

(2) maintenance of a free and open information network with all Government-identified associate Contractors;

(3) delineation of detailed interface responsibilities;

(4) entering into a written agreement with the other Associate Contractors setting forth the substance and procedures relating to the foregoing, and promptly providing the Agreements Officer/Procuring Contracting Officer with a copy of same; and,

(5) receipt of proprietary information from the Associate Contractor and transmittal of Contractor proprietary information to the Associate Contractors subject to any applicable proprietary information exchange agreements between associate contractors when, in either case, those actions are necessary for the performance of either.

(d) In the event that the Contractor and the Associate Contractor are unable to agree upon any such interface matter of substance, or if the technical data identified is not provided as scheduled, the Contractor shall promptly notify the ARPA-H PM. The Government will determine the appropriate corrective action and will issue guidance to the affected Contractor.

(e) The Contractor agrees to insert in all subcontracts hereunder which require access to proprietary information belonging to the Associate Contractor, a clause which shall conform substantially to this language, including this paragraph (e).

(f) No human subjects research data can be shared between BLANK performers without prior IRB and OHRP approval.

(g) Associate Contractors for this research effort include:

Technical Area	Contractor Name and Point of Contact (POC)
	PERFORMER NAME: **ADDRESS**: **Performer's Administrative/Contracting Name:** **Phone Number:** **Email**: **Performer's Technical POC** **Name**: **Phone Number**: **Email**: **AGREEMENT NUMBER**:
	PERFORMER NAME: **ADDRESS**: **Performer's Administrative/Contracting Name**: **Phone Number**: **Email**: **Performer's Technical POC** **Name**: **Phone Number**: **Email**: **AGREEMENT NUMBER**:
	PERFORMER NAME: **ADDRESS**: **Performer's Administrative/Technical POC** **Name**: **Phone Number**: **Email**: **AGREEMENT NUMBER**:
	PERFORMER NAME: **ADDRESS**: **Performer's Administrative/Contracting Name**: **Phone Number**: **Email**: **Performer's Technical POC**

	Name: **Phone Number:** **Email:** **AGREEMENT NUMBER**:
	PERFORMER NAME: **ADDRESS**: **Performer's Administrative/Contracting** **Name**: **Phone Number**: **Email**: **Performer's Technical POC** **Name**: **Phone Number:** **Email:** **AGREEMENT NUMBER**:
	PERFORMER NAME: **ADDRESS**: **Performer's Administrative/Contracting** **Name**: **Phone Number**: **Email**: **Performer's Technical POC** **Name**: **Phone Number:** **Email:** **AGREEMENT NUMBER**:

ATTACHMENT 1:
TASK DESCRIPTION DOCUMENT

Task 1:

Subtask Task 1-A:		
Objective	**Task Description**	**Location**
Primary Organization Responsible		
Deliverable(s) (with associated IP assertion if less than Unlimited Rights)		
Human Subjects or Animal Research?		
Milestones 1		

Subtask Task 1-B:		
Objective	**Task Description**	**Location**
Primary Organization Responsible		
Deliverable(s) (with associated IP assertion if less than		

Unlimited Rights)	
Human Subjects or Animal Research?	
Milestones	

Subtask 1-C:		
Objective	**Task Description**	**Location**
Primary Organization Responsible		
Deliverable(s) (with associated IP assertion if less than Unlimited Rights)		
Human Subjects or Animal Research?		
Milestones		

Subtask 1-D:		
Objective	**Task Description**	**Location**
Primary Organization Responsible		

Deliverable(s) (with associated IP assertion if less than Unlimited Rights)	
Human Subjects or Animal Research?	
Milestones	

Subtask 1-E: Secure Deployment of Patched Binaries		
Objective	**Task Description**	**Location**
Primary Organization Responsible		
Deliverable(s) (with associated IP assertion if less than Unlimited Rights)		
Human Subjects or Animal Research?		
Milestones		

Subtask 1-F:		
Objective	**Task Description**	**Location**
Primary Organization Responsible		
Deliverable(s) (with associated IP assertion if less than Unlimited Rights)		

Human Subjects or Animal Research?	
Milestones	

Task 2: Task 2:

Subtask 2-A:		
Objective	**Task Description**	**Location**
Primary Organization Responsible		
Deliverable(s) (with associated IP assertion if less than Unlimited Rights)		
Human Subjects or Animal Research?		
Milestones		

Subtask 2-B:		
Objective	**Task Description**	**Location**
Primary Organization Responsible		

Deliverable(s) (with associated IP assertion if less than Unlimited Rights)	
Human Subjects or Animal Research?	
Milestones	

ATTACHMENT 2
REPORT REQUIREMENTS

A. REPORTS

All reports required by this Agreement shall be digitally sent to BLANK, in addition to any other submission requirements.

On or before ninety (90) calendar days after the effective date of the Agreement and thereafter throughout the term of the Agreement, the Performer shall submit or otherwise provide a report. One (1) copy shall be submitted or otherwise provided to the ARPA-H PM, one (1) copy shall be submitted or otherwise provided to the ARPA-H AO, one (1) copy shall be submitted or otherwise provided to ARPA-H AOR, and one (1) copy shall be digitally sent to BLANK. The report will have two (2) major sections.

1. **Technical Status Report**. The technical status report will detail technical progress to date and report on all problems, technical issues, major developments, and the status of external collaborations during the reporting period.

2. **Special Technical Reports.** As agreed, to by the Performer and the ARPA-H AOR, the Performer shall submit or otherwise provide to the ARPA-H AOR, ARPA-H PM, and ARPA-H AO, and digitally sent to BLANK, one (1) copy each of special reports on significant events such as significant target accomplishments by the Performer, significant tests, experiments, or symposia.

3. **Business Status Report.** The business status report shall provide summarized details of the resource status of this Agreement, including the status of the Performer contributions. This report will include an accounting of current expenditures as outlined in the Annual Program Plan. Any major deviations, over plus or minus 10%, shall be explained along with discussions of the adjustment actions proposed. The report will also include an accounting of any interest earned on Government funds. The Performer is reminded that interest in amounts greater than five hundred dollars ($500.00) per year is not expected to accrue under this Agreement. In the event that this interest does accrue on Government funds, the Performer is required to provide an explanation for the accrual in the business report.

4. **Milestone Reports.** The Performer shall submit or otherwise provide to the ARPA-H AOR, ARPA-H PM, and ARPA-H AO, and digitally send to BLANK, documentation describing the extent of accomplishment of Payable Milestones. This information shall be as required by Article 5 and shall be sufficient for the ARPA-H AOR to reasonably verify the accomplishment of the milestone of the event in accordance with the TDD.

5. **Final Report.** The Final Report is the last milestone for the completed Agreement.

    1. The Performer shall submit or otherwise provide a Final Report making full disclosure of all major developments by the Performer upon completion of the Agreement or within sixty (60) calendar days of termination of this Agreement pursuant to Article 2, Paragraph B. One (1) copy shall be submitted or otherwise provided to the ARPA-H AOR, one (1) copy shall be submitted or otherwise provided to the ARPA-H PM, and one (1) copy shall be submitted or otherwise provided to the ARPA-H AO.

6. **Patent Reports.** See Article 7. All required reporting shall be accomplished, to the extent possible, using the i-Edison reporting website: https://www.nist.gov/iedison. To the extent any such reporting cannot be carried out by use of i-Edison, reports and communications shall be submitted to the AO.

B. DATA MANAGEMENT AND SHARING PLAN

(NOTE: This is a one-time submittal due NLT 30 days after award)

1. A Data Management Sharing Plan (DMSP) requires three things: that researchers think about how they will manage, document, and share their scientific research data[1] before beginning data collection; that they show ARPA-H their thought process in the formal DMSP, and that they make their research data as publicly available as possible within a reasonable time frame. DMSP submitted to ARPA-H should describe at a minimum the data type, related tools, software and/or code, standards, data preservation, access and associated timelines, access, distribution or reuse considerations and oversight of data management and sharing. See NOT-OD-21-014 for supplemental information to help in the development of the DMSP.

2. The Performer shall submit an electronic copy of their DMSP no later than 30 calendar days after award of this Agreement to the ARPA-H AOR, ARPA-H PM, ARPA-H AO.

C. ANNUAL PROGRAM PLAN DOCUMENT

The Performer shall submit or otherwise provide to the ARPA-H AOR, ARPA-H PM, and ARPA-H AO, and digitally send to BLANK, one (1) copy each of a report which describes the Annual Program Plan as described in Article 3, Section B.

D. EXECUTIVE SUMMARY

The Performer shall submit a one- to two-page executive-level summary of the major accomplishments of the Agreement and the benefits of using the other transactions authority. This summary shall include a discussion of the actual or planned benefits of the technologies for the commercial sectors. One (1) copy shall be submitted to the ARPA-H AO.

[1] Data commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. This covers both quantitative and qualitative data, and applies to all data types including image, audio, and video data of all file formats and sizes. It explicitly does not apply to laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens.

ATTACHMENT 3:
SCHEDULE OF MILESTONES AND PAYMENTS

NOTE: The following chart will detail the list of milestones. Each milestone will mark the completion of a measurable event (i.e., completing a baseline execution plan, completing measurable events in the performance of the research and development of the technology, completing, and submitting the final report, etc.). Status reports cannot be milestones. The milestone description will show how the milestone will be demonstrably completed. Payments associated with each milestone must reflect the actual comprehensive costs to achieve milestone completion.

[Document Date]

A. Agreement Term:

The term of the Agreement commences on the effective date of the Agreement and continues for INSERT # OF MONTHS thereafter.

B. Deliverables and Payment Schedule:

Base

Milestone	Task(s)	Due Date (Months after award)	Milestone Definition	Payment
1			**Milestone Name/Description** *Exit Criteria:* *Deliverables:* •	
Funding TBD:				
2			**Milestone Name/Description** *Exit Criteria:* *Deliverables:* •	
Funding TBD:				
3			**Milestone Name/Description** *Exit Criteria:* *Deliverables:* •	
Funding TBD:				

ATTACHMENT 4:
AGREEMENT OFFICER'S REPRESENTATIVE

ATTACHMENT 5:
PROPERTY/EQUIPMENT

Below is a list of equipment proposed to be purchased by the Performer with an acquisition value of greater than $5,000. The Government will the Disposition of Property to all equipment purchased under this Agreement in accordance with the terms and conditions of Article 9.

Item Description	Unit Price	Quantity	Total Projected Cost
	$		$
	$		$
	$		$