AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT D CODE	PAGE OF PAGES
	1 176

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00004	See Block 16C		

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
National Institutes of Health National Cancer Institute Bldg 1050 Frederick, MD 21702	NCI-BLDG 427	National Institutes of Health National Cancer Institute Bethesda, MD 20892-7511	NCI

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
LEIDOS BIOMEDICAL RESEARCH, INC.:1107088 P.O. BOX B FREDERICK MD 217029242	(x)	9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75N91019D00024
		10B. DATED *(SEE ITEM 13)* 06/26/2019

CODE	FAC LITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing tems 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FA LURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER If by virtue of this amendment you desire to change an offer already submitted , such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNT NG AND APPROPRIATION DATA *(If required)*
See Schedule

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIF ED TO REFLECT THE ADM NISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH N ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	FAR 43.103(a).
	D. OTHER *(Specify type of modification and authority)*

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

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

The purpose of this bilateral modification is to make updated changes to Invoicing Instructions, update many clauses in accordance with the DGS Workform updates, and add Attachment 24, Electronic Invoicing Instructions for NIH Contractors/Vendors. ARTICLES G.4., G.5., Section I and Section J, are modified. All other terms and conditions remain unchanged.

Payment:
Approved By, NCI Branch D Invoices
Paid By: NIH Commercial Accounts Br
2115 East Jefferson St, MSC 8500
Room 4B-432
Bethesda, MD 20892-8500

Continued ...

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACT NG OFFICER *(Type or print)*
[redacted]	SCOTT P. KEASEY
1[redacted]	1[redacted]

15C. DATE SIGNED	
03/05/2021	

NAME OF OFFEROR OR CONTRACTOR
LEIDOS BIOMEDICAL RESEARCH, INC.:1107088

ITEM NO. (A)	SUPPL ES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 06/26/2019 to 06/25/2021				

Contents

PART I - THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Contractor shall, in accordance with the provisions of this contract, support the missions and programs assigned under contract with the National Cancer Institute and manage and operate the National Cancer Institute's Federally Funded Research and Development Center (FFRDC)/Frederick National Laboratory for Cancer Research (FNLCR). The purpose of the FFRDC is to provide a unique biomedical research and development resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis, and treatment of cancer, Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS), and other diseases in support of the NCI, NIAID, other NIH ICs and other government agencies. The FFRDC serves as a flexible, quick-response mechanism to accomplish the most urgent national/global health initiatives for the NCI/NIH and other government agencies.

ARTICLE B.2. SPONSORING AGREEMENT

The Frederick National Laboratory for Cancer Research (FNLCR) is Government-Owned Contractor-Operated (GOCO), Federally Funded Research and Development Center (FFRDC), sponsored by NIH under contract by NCI and established in accordance with Federal Acquisition Regulation (FAR) 35.017. This sponsoring agreement between NCI/NIH and the FNLCR facilitates the long-term relationship, establishes the FNLCR's mission, and ensures periodic reevaluation of the FFRDC to ensure special research and development needs continue to be met.

In accordance with FAR 35.017-1(a), a sponsoring agreement may take various forms and may be included in a contract between the Government and the FFRDC. This Article B.2, which references and incorporates other terms and conditions set forth in the contract, constitutes the sponsoring agreement for this FFRDC.

In accordance with FAR 35.017-1(e), the term of this sponsoring agreement will not exceed 5 years, but can be renewed, as a result of periodic review, in increments not to exceed 5 years. This sponsoring agreement is scheduled for periodic reevaluation prior to May 2021 to ensure special research and development needs continue to be met.

A. **Statement of Purpose and Mission of the FFRDC**

The purpose of the FNLCR is to provide a unique biomedical resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis, and treatment of cancer, Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS), and other diseases. The FFRDC's contract Statement of Work (SOW) encompasses various research support programs, projects, and activities including, but not limited

to: basic, translational, clinical and animal research and research support.

B. **Provisions for Orderly Termination or Nonrenewal of the Agreement, Disposal of Assets, and Settlement of Liabilities**

This contract and the Contractor's operation of the FNLCR are based on expectations of a long-term and continuing relationship between the parties. NIH/NCI will use its best efforts to inform the Contractor as far as possible in advance if it concludes that such a long-term relationship is no longer in the best interest of the Government however, the notification requirements at FAR 52.217-9(a) remain unchanged.

This Contract contains the general provisions and other special provisions/clauses which describe the process for orderly termination or nonrenewal of this Agreement including disposal of any assets and settlement of liabilities. Responsibility for capitalization of the FFRDC and ownership of the assets rests with the Government.

In the event of termination of the sponsoring agreement and resultant termination of the contract, the Government shall ensure the minimum quantity stated in Article B.3. has been paid to the Contractor. Additionally, task orders issued hereunder are subject to termination provisions.

In the event of such termination or of the expiration or non-renewal of this Agreement and contract, all items that were furnished by the Government or purchased by the Contractor and charged to the contract are the property of the Government and will be managed/disposed of in accordance with FAR 52.245-1.

In the event of termination or nonrenewal of the sponsoring agreement the Government shall deduct from the amount due to the Contractor all unliquidated advance payments as required by FAR clause 52.232-12. In the event of termination or nonrenewal, ownership and management of all work in process, intellectual property, CRADA funds, royalty funds, rights to uncollected royalties and related records shall be transferred to a successor Contractor or the Government. In the event of termination, all source code and object code developed, modified, or enhanced under this Contract shall remain in place at the FNLCR unless different disposition is directed by the Contracting Officer.

In addition to the provisions identified herein, the Government may recognize a third party as the successor in interest to the Contract when the third parties' interest in the Contract arises out of the transfer either of all the assets of the Contractor or all of that part of the Contractor's assets involved in the performance of the Contract. In the event of a successor in interest it is the Government's intent that all assets and liabilities would novate to the successor including all subcontracts having anticipated completion dates beyond the expiration date of the Contract.

The Contractor shall transfer funds to the successor Contractor(s) in an amount equal to the dollar value of the accrued vacation liability. The successor Contractor shall assume the Employee Savings

Plan and the Defined Benefit Retirement Plan and the incumbent 401(k) Plan. The successor Contractor shall assume the Plans' respective trusts and assets and become responsible for any and all obligations to participants in the Plans as a result of the transfer in total to the successor Contractor of assets and liabilities of the plans. The amount of pension liability shall be based on the most recent actuarial calculation completed by the plan actuary. The amount of the assets that shall be transferred by the Contractor to the successor Contractor shall equal the assets in the Plans' respective Trusts. For purposes of thisContract, the term “successor contractor” shall be understood and agreed to include the incumbent contractor awarded a follow-on contract to perform substantially the same work required under this contract.

The Government shall approve assets and liabilities as being properly calculated in compliance with applicable Cost Accounting Standards.

C. **Retained Earnings Identification, and Plan for Use and Disposition**

The Contractor shall identify all retained earnings on a periodic basis, but not less than once per year, including a plan for the use and disposition in the events of termination or nonrenewal of the Agreement. In the context of this clause, “retained earnings” shall be defined as those items identified in section (b) of this Article including ownership and management of all work in process, intellectual property, Government CRADA funds, royalty funds and uncollected royalties. It is understood and agreed that “Retained Earnings” expressly excludes any and all fixed fee earned by the Contractor under this contract.

D. **Prohibition Against Competition**

The Contractor shall not compete with any non-FFRDC concern in response to a Federal agency request for proposal for other than the operation of this FFRDC. This prohibition is not applicable to the Contractor's parent organization, if any, or other subsidiary of the parent organization in its non-FFRDC operations. This prohibition does not apply to requests for information, qualifications or capabilities as those can be answered unless otherwise restricted by the Contracting Officer.

E. **Accepting Work from Other than the Sponsor**

The Government, not the contractor, has complete discretion about whether to accept work from other than NIH. Therefore, the Contractor shall not accept work from a nonsponsoring Federal agency, i.e., an agency other than the NIH, unless accepted by the Contracting Officer’s Representative (COR) and approved by the Contracting Officer. Work from nonsponsoring Federal agencies may be accepted by the COR and approved by the Contracting Officer only if such work falls within the purpose, mission, general scope of effort, or special competency of the FFRDC. Furthermore, any such use of the FFRDC by a nonsponsoring Federal agency must be in accordance with 48 CFR 17.502-2, The Economy Act. Prior to acceptance by the COR and approval by the Contracting Officer, the nonsponsoring Federal agency shall provide all information and documentation requested by the COR and Contracting Officer, including but not limited to

confirmation that the requested work would not place the FFRDC in direct competition with domestic private industry.

F. **Advance Understandings**

Cost elements which require advance agreement are addressed herein under Article B.4. Advance Understandings.

ARTICLE B.3. PRICES/COSTS

This is an Indefinite Quantity contract as contemplated by FAR 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of $ 350,000 (minimum) nor more than a total of $ 6,600,000,000 (maximum) for successful performance of this contract.

A. The minimum and maximum set forth in this ARTICLE will cover the ordering period June 26, 2019 through June 25, 2024, should all options be exercised.

B. The Government will issue Task Orders based on the work described in SECTION C of this contract.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

A. Indirect Rates and Labor Rate Ranges

1. Establishment of Indirect Rates

Indirect costs are funded in accordance with Section J, Attachment 1; however, the Contractor shall not bill or be reimbursed for indirect costs until such time as an indirect cost proposal has been submitted to the cognizant office responsible for negotiating the indirect cost rates, unless a temporary billing rate(s) has been included herein. Unless otherwise specified below, the indirect cost rate proposal shall be submitted no later than thirty (30) days after the date of contract award.

The Contractor may bill indirect costs and direct labor rates at the temporary billing rates specified in Section J, Attachment 1, until such time as indirect costs have been established, provided, that the Contractor's indirect cost proposal is submitted to the cognizant office responsible for negotiating indirect costs no later than thirty (30) days after the date of contract award. If, the indirect cost proposal is not submitted in a timely manner, any temporary indirect costs billed after this due date will be suspended until such time as the indirect cost proposal is submitted.

2. Management of Indirect Rates

The Contractor is responsible for managing all indirect rates as set forth under Article B.4.A.1. This responsibility includes operating and managing all indirect functions and resources required in support of the contract and Task Orders awarded thereunder. Such resources include, but are not limited to, both fixed and variable indirect employees, budgets and other costs required in support of indirect operations.

The following functions are considered indirect; prime contract administration, project management oversight, finance and project control, accounting, human resources, support of contractor business enterprise systems, technology transfer, partnership development, executive leadership, procurement, subcontract administration, export control, public affairs and communications, compliance and risk management, clinical regulatory oversight, occupational health, safety officers, conference planning and travel administration. Staff in these functional areas ensure operation of the FFRDC in a manner compliant with federal or state legal and regulatory statutes. Liability insurance and all employee benefits are considered indirect costs.

All indirect fixed and variable costs shall be included in submission of any interim indirect billing rates provided to the responsible Contracting Officer for review and approval.

The Contractor shall provide the Government with an annual Operations Plan in the mutually agreed upon format and frequency as a notification. Such plans are provided for informational purposes only and should not include budget information.

B. Insurance

The Contractor is authorized to acquire the following types of insurance coverage subject to Contracting Officer Authorization (COA) except that any insurance required by law shall not require COA. The Contractor is authorized to utilize existing, or to acquire additional insurance coverage required under fixed price task orders in accordance with FAR 52.228-5 as an allowable cost subject to COA except that any insurance required by law shall not require COA.

1. General Liability (both Domestic and International); 2. Automobile Liability; 3. Umbrella/Excess Liability; 4. Fiduciary Bond; 5. Fidelity Bond; 6. Group Travel; 7. Medical Malpractice; 8. Medical Products Liability for Therapeutics, Diagnostics, and Vaccines; 9. Professional Liability-OHS Clinic; 10. Physicians Malpractice; and 11. Leased Facilities.

The allowable costs associated with the insurance coverage authorized above shall not include "mark-up" of any costs, e.g., General and Administrative costs (G&A), allocated from Leidos (Corporate) to the Contractor with respect to acquisition of approved insurance policies covering activities under this contract.

C. Licenses and Permits

The Contractor agrees to obtain and maintain licenses and permits as identified in Section J, Attachment 2, Licenses and Permits, and notify the Government if revisions or additions to Attachment 2 are required.

D. On-site Corporate Authority

The following listed full-time individuals shall have the authority to represent and commit the Contractor in dealings with the Government. One of these employees shall be available on any given working day of the contract period. The Contractor shall notify the Government of any changes to this listing.

Name of Individual(s)	Position
[redacted]	[redacted]

E. Discretionary Leave

The Contractor will be held accountable to complying with their Discretionary Leave Policy. The Contractor's President/CEO shall notify the Contracting Officer via email prior to the use of discretionary leave. The Contractor shall request Contracting Officer authorization for any changes to the discretionary leave policy.

F. Non-Personal Services and Inherently Government Functions

1. Pursuant to FAR Subpart 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the Contracting Officer's Representative (COR) to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All individual employee assignments, and daily work direction, shall be given by the applicable employee supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.
2. Pursuant to FAR Subpart 7.5, the Contractor shall not perform any inherently Governmental actions under this contract. No Contractor employee shall hold him or herself out to be a

Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way to change the contract and that if the other contractor believes this communication to be a direction to change their contract, they should notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

3. The Contractor shall insure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of the contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

G. Steam Production Plants

It is understood and agreed that Steam Generation (North and South) plants constructed and operated by APS Cognenix on behalf of its parent Potomac Edison, through the Energy Basic Ordering Agreement #97CXS0272A (Delivery Order NCI-2005-07), shall be operated by APS Cognenix pursuant to its subcontract with the Contractor. The Government acknowledges that this project will be viewed as any other "maintained facility" on the NCI- FNLCR campus in accordance with the terms of this contract, and the Contractor assumes no additional liability beyond that provided for by the provisions of this contract, and for the willful misconduct or gross negligence of the Contractor. Remedies for plant failures are outlined in the Delivery Order modification to the Energy BOA identified above and the Feasibility Study proposal included therein. The Contractor has not acquired any additional insurance to cover losses of the steam facility or related losses due to the loss of steam to operating labs at the NCI Campus at Frederick.

H. HPV Serology Standardization Project

The Human Papillomavirus (HPV) Serology Project requirement was funded in part by a gift from the Gates Foundation (the "Foundation") to NCI. The Contractor and NCI agree that the Project activities shall not involve clinical trials, trials involving human subjects, post-approval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services (individually or collectively, "Indemnified Activities"). The Contractor represents and warrants that it shall not engage in and will ensure that no funds are used for any Indemnified Activities in fulfillment of its obligations under the Project.

I. Retirement Programs

The Contractor shall maintain retirement programs defined below and consistent with respective plan documents for plan participants working at the Frederick National Laboratory for Cancer Research (FNLCR), a Government Owned – Contractor Operated (GOCO), Federally Funded

Research and Development Center (FFRDC). Retirement Programs A and B, as defined below, exist for the exclusive benefit of Contractor employees of the FNLCR and have been and will continue to be sponsored by the Contractor on behalf of NCI, pursuant to relevant requirements and during the term of the Contract.

Retirement Program A—Defined Benefit Plan & Employee Savings Plan [Legacy 401(k)]

Program A is a Qualified Off-Set Arrangement authorized by the Tax Reform Act of 1986, Pub. L. No. 99-514, Special Rule for Qualified Off-Set Arrangements, Section 1116(f)(5). Program A was adopted effective September 26, 1982 and closed to new entrants effective July 1, 2006 and was amended effective June 27, 2014 to freeze benefit accruals for all participants, other than those who, as of the effective date, either had attained age 55 and 10-years of service or had attained age 65 and 5 years of service ("Grandfathered Participants"). The 2014 plan amendment was not deemed to be a "curtailment of benefits" as that term is defined in CAS 413-30(a)(7), as ongoing plan participants continued to accrue material benefits under Plan A.

Retirement Program B—401(k) Plan

This is a 401(k) Defined Contribution Plan (New 401(k)). It is the sole retirement program available to Contractor employees who accepted an offer of employment on or after July 1, 2006; in addition, active staff who previously participated in Plan A, but failed to qualify with the Grandfathering provisions adopted at the time of the 2014 plan amendment, became eligible to participate in Plan B on June 28, 2014 via the amendment executed on June 9, 2014.

Since program inception, the Government and each Contractor Operator, have agreed and acted accordingly, that the Contractor Operator would sponsor and administer the Defined Benefit Plan on behalf of the Government. With respect to the Defined Benefit Plan, the June 24, 1986 Senate Colloquy to Public Law 99-514 states that, in the case of individuals working at the FNLCR, the employer is the facility itself, without regard to the particular contractor in charge of facility operations.

It is the mutual intent of the parties that the FNLCR Retirement Programs A and B continue as ongoing retirement programs over the term of this contract. The parties agree that this contract, because it relates to operating a FFRDC, is the only cost objective to which the costs of Retirement Programs A and B will be allocated for purposes of government contract cost accounting requirements, including CAS 412 and 413. Further, the parties agree that all allowable costs related to Program A and B, including all post-curtailment and plan termination costs, are allocable 100% to the applicable task order(s) issued pursuant to this contract. Consistent with this intent, the Contractor will continue to sponsor and administer Retirement Programs A and B during the term of this contract. The parties' responsibilities regarding Retirement Programs A and B under this contract, including Government reimbursement to Contractor for all allowable program costs, i.e., costs of the on-going plan (e.g., costs of actuarial gains and losses and plan maintenance costs); costs of plan funding (e.g., prepayment credits); costs of administering (e.g., all costs, such as litigation costs, relating to plan participant rights under a program); or costs of terminating

Retirement Programs A and/or B, will be specifically addressed in the first NCI Operational Task Order issued under the contract. Based on mutual agreement of the parties to enact a termination of either Plan A and/or Plan, such termination will be executed through award a stand alone task order.

J. Fixed Fee
The following represents the negotiated fixed fee to be applied to all Cost Plus Fixed Fee Task Orders issued hereunder: [redacted]. The parties agree that a fixed fee of [redacted] shall be applied to the estimated cost of each task order at the time of obligation. The fixed fee will not vary based on actual costs incurred unless the Contracting Officer modifies the task order to add new work.

K. The Contractor shall obtain Contracting Officer approval prior to taking the following actions. The following is a non-exclusive list of applicable actions:
1. All name changes to Leidos Biomedical Research, Inc. labs, programs, centers, etc.
2. All space assignments

L. It is agreed and understood that all number of days stated within this contract are assumed to be business days unless otherwise specified.

M. Determination of Exceptional Circumstances
In accordance with FAR 52.27.304-1(b) and 27.303(e)(1)(ii), the National Cancer Institute requested and received approval for the use of deviated FAR clauses in this contract. The following deviated FAR clauses are incorporated by reference and are included in full text as Section J, Attachment 3.

FAR **52.227-13 (Deviation) Patent Rights--Ownership by the Government** (April 2017)
[**Patent Rights-Prime Contractor**];
FAR **52.227-11 (Deviation) Patent Rights--Ownership by the Contractor** (April 2017)
[**Conditional Ownership by the Contractor--Contractor CRADAs**]; and,
FAR **52.227-11 (Deviation) Patent Rights--Ownership by the Contractor** (April 2017)
[**Patent Rights-Use of Third-party Technology and Information or Intramural/repurposed Drug Development by Subcontractors**].

ARTICLE B.5. PROVISIONS APPLICABLE TO DIRECT COSTS

A. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses, ALLOWABLE COST AND PAYMENT, and FIXED FEE, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

1. Conferences and meetings;
Defined as: All Symposia, Seminars, Conferences and Meetings as per the latest guidance in the HHS Efficient Conference Spending Policy and incorporated guidance on HHS Policy on Use of

Appropriated Funds for Conferences and Meeting Space.

2. Food for Meals, Light Refreshments & Beverages;

3. Promotional Items including, but not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees;

4. Acquisition, by purchase or lease, of any interest in real property;

5. Special rearrangement or alteration of facilities; *See Article H.73.B, Work Orders.*

6. Foreign travel
   All foreign travel requires Contracting Officer Authorization (COA). All travel costs exceeding those authorized under the Federal Travel Regulations (FTR) must be justified in writing to the Contracting Officer for Contracting Officer Authorization:

   No funds provided under this contract shall be used for reimbursement of travel expenses incurred by Government employees. Neither shall contract funds provided under this contract be used for travel of other non-contractor employees without the prior approval of the Contracting Officer. The only exceptions are travel associated with subcontracts based on approved purchase requests that include costs for travel.

   In the event a Contractor employee requesting travel is also employed on another contract, the Contractor must identify the other contracts by Agency and contract number in a letter to the Contracting Officer. Such letter shall include a written statement from the cognizant Contracting Officer of the other Agency that the employee's travel is for the benefit of this contract and therefore no charges for time or travel will be made to another contract;

7. Consultant Costs;

8. Subcontract Costs;

9. Accountable Government Property 1) “capital equipment” (defined as non-expendable personal property with an acquisition cost of $5,000 or more) and 2) "sensitive items" (defined as items of personal property supplies and equipment that are highly desirable and easily converted to personal use), regardless of acquisition value;

10. Dispensation of Government furnished, or Contractor acquired property under this contract to include:
    a. Sale of Scrap
    b. Sale and Barter
    c. Transfer of Property
    d. Educational Institution Screening Request

e. Educational Institution Donation Request
f. Relief of Accountability/Abandonment (including notification of proper disposal per federal, state, and local laws when property has been exposed to radiation)
g. Relief of Accountability – Government Fleet Vehicles;

11. Severance pay, early retirement, or voluntary termination incentives not otherwise provided for in the Contractor's Human Resource policy;

12. Acquisition, by purchase or lease, of any motor vehicle;

13. For any proposed legal instrument between the Contractor and its parent organization including all businesses in which the parent organization is known to have a controlling interest, including but not limited to affiliates and subsidiaries;

14. Changes/renewals or additions to insurance coverage;

15. Request for guest researcher;

16. Technology transfer agreements:
    a. cCRADA
    b. mCRADA
    c. Additions to Technical Services Agreement (TSA) list
    d. Collaboration agreement
    e. Beta-test agreement.

17. Travel Costs
    The Contractor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) § 31.205-46, Travel Costs.

18. Independent Research
    No independent research, with the exception of the LDER program, will be performed under this contract without prior authorization from the Contracting Officer.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated June 26, 2019, attached hereto and made a part of this Contract (See SECTION J, Attachment 4).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Task Orders issued hereunder will identify task order specific reporting requirements.

A. Technical Progress Reports (Applicability specified at task order level)

In addition to the required reports set forth elsewhere in this contract, the preparation and submission of regularly recurring Technical Progress Reports will be specified at the task order level. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of the reports will be determined within each task orders. [Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

1. Reporting on Dual Use Research of Concern (Applicability specified at task order level)

    a. Progress Report
    For work involving an agent or toxin identified in the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern or "DURC policy" (see http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf), the contractor shall report the following information in the Annual/Semi-Annual/Quarterly/Monthly Progress report:
        i. Identification of agents or toxins that are listed in the DURC policy and used in research funded in this contract, and;
        ii. Proposed modifications, if any, to the risk mitigation plan.
    b. Special Notifications
    The contractor shall report to the Contracting Officer's Representative, within 30 calendar days of:
        i. Any change in the status of the DURC project funded under this contract (including whether the research is determined by the contractor's institutional review entity to no longer meet the definition of DURC);
        ii. Details of any changes to risk mitigation plans (such changes need to be pre-approved by the Contracting Officer's Representative), or;
        iii. Instances of noncompliance with the DURC policy, as well as mitigation measures undertaken by the contractor to prevent recurrences of similar noncompliance.

2. Annual Technical Progress Report for Clinical Research Study Populations (Applicability specified at task order level)

   The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations (when appropriate) for each study being performed under this task order. The Contractor shall submit this information in the format indicated in the attachment entitled, "Cumulative Inclusion Enrollment Report," which is set forth in SECTION J, Attachment 5 of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report. If the clinical study(s) involves US and non-US sites, the US sites and non-US sites should be reported on separate Cumulative Inclusion Enrollment Reports.

   The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract.

   In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website: http://grants.nih.gov/grants/funding/women_min/women_min.htm .

   For NIH-defined Phase III Clinical Trials: Include a description of the plans for valid analysis in the study design and outcomes. This includes designing the study in a manner that potential differences, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol could be conducted. Also, provide a description of any analyses by sex/gender, race, and/or ethnicity, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender, race and/or ethnicity.

3. Final Report (Applicability specified at task order level)

   This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. A/An [Annual/Semi-Annual/Quarterly/Monthly] report will not be required for the period when the Final Report is due.

4. Summary of Salient Results (Applicability specified at task order level)

   As identified in each task order, as applicable, the Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved

during the performance of the contract. This report will be required on or before the expiration date of the task order.

5. Reporting on Select Agents or Toxins and/or Highly Pathogenic Agents (Applicability specified at task order level)

   For work involving the possession, use, or transfer of a *Select Agent or Toxin* and/or a *Highly Pathogenic Agent*, the following information shall also be included in each [Annual/Semi-Annual/Quarterly/Monthly] Progress Report:

   a. Any changes in the use of the Select Agent or Toxin including initiation of "restricted experiments," and/or a Highly Pathogenic Agent, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or institutional biosafety official.

   b. If work with a new or additional *Select Agent or Toxin* and/or a Highly Pathogenic Agent will be conducted in the upcoming reporting period, provide:
      i. A list of each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent that will be studied;
      ii. A brief description of the work that will be done with each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent and whether or not the work is a Select Agent or Toxin restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html) or listed on the U.S. National Select Agents Registry restricted experiments website (http://www.selectagents.gov/index.html);
      iii. The name and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location or different location.
      iv. For work with Select Agents performed in the U.S. provide documentation of registration status of all domestic organizations where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior NIAID approval is required.

      If the IBC or equivalent body or institutional biosafety official has determined, for example, by conducting a risk assessment, that the work that has been performed or is planned to be performed under this contract may be conducted at a biocontainment safety level that is lower than BSL3, a statement to that affect shall be included in each [Annual/Semi-Annual/Quarterly/Monthly] Progress Report.

      If no work involving a Select Agent or Toxin and/or a Highly Pathogenic Agent has been performed or is planned to be performed under this contract, a statement to

that affect shall be included in each [Annual/Semi-Annual/Quarterly/Monthly] Progress Report.

6. Cost, Schedule, Performance Reports (Applicability specified at task order level)
The Contractor shall submit recurring cost, schedule, performance reports. The frequency and specific content of these reports will be determined per task order for specific task order requirements. The reports shall comprehensively describe cost, schedule, and performance metrics and issues. The reports shall include the following information:

   a. An estimate at completion (EAC) shall be calculated through the reporting period. Current spending (and staff level-of-effort, as applicable) through the reporting period shall be compared to estimated spending rate (and staff level-of-effort set at the beginning of the project/task order. Issues related to spending rate (ahead of spending rate/staff level-of-effort or behind) shall be discussed at a summary level.

   b. Current schedule/milestones through the reporting period shall be compared to the estimated schedule/milestones set at the beginning of the project/task order. Issues related to schedule (ahead of schedule or behind) shall be discussed at a summary level.

   c. Performance issues shall be discussed and linked to cost/schedule issues. Potential risks identified during the performance of the project/task order are discussed as they are encountered or mitigated. Proactive solutions to performance issues should also be discussed.

B. Other Reports/Deliverables

1. Reporting of Financial Conflict of Interest (FCOI)

   All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in Electronic format. Thereafter, reports shall be due in accordance with the regulatory compliance requirements in 45 CFR Part 94.

   45 CFR Part 94 is available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45 . See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

   (Reference subparagraph g. of the INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST Article in SECTION H of this contract.)

2. Report of USDA-Designated Biobased Products

   In accordance with FAR clause 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts, the contractor shall report to https://www.sam.gov any USDA-designated biobased products purchased during the period of October 1-September 30 of each contract year. This report shall be submitted no later than October 31 of each year during contract performance and at the end of contract performance.

3. Source Code and Object Code

   All source code and object code developed, modified, and/or enhanced under this contract is the property of the Government. Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

4. Information and/or Physical Security

   The Contractor shall submit the following reports as required by the HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS Article in SECTION H of this contract and in accordance with HHS Enterprise Performance Life Cycle Policy, https://www.hhs.gov/sites/default/files/eplc-policy-dec-2016.pdf. The Contractor shall comply with the below requirements for all new systems and report on the base IDIQ Contract for contract-wide systems/requirements and per task order for specific task order systems/requirements. For any legacy systems, applications, and computers, the Contractor shall document their plan for bringing them into compliance and submit this plan to the Government within 30 calendar days of contract award. For both existing legacy systems and new systems, the Contractor shall document non-compliance issues in accordance with NIST guidance.

   a. Security Assessment and Authorization (SA&A)- A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s). The Contractor shall conduct the SA&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).

   For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such.

   NIH acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the

system security and privacy controls are implemented and operating effectively.

b. SA&A Package Deliverables - The Contractor (and/or any subcontractor) shall provide an SA&A package in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The following SA&A deliverables are required to complete the SA&A package.

   i. System Security Plan (SSP) - due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The SSP shall comply with the NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems, the Federal Information Processing Standard (FIPS) 200, Recommended Security Controls for Federal Information Systems, and NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline requirements, and other applicable NIST guidance as well as HHS and NIH policies and other guidance. The SSP shall be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP shall provide an overview of the system environment and security requirements to protect the information system as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP no less than annually thereafter.

   ii. Security Assessment Plan/Report (SAP/SAR) - due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The security assessment shall be conducted by the assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and NIH policies. The assessor will document the assessment results in the SAR.

   The NIH should determine which security control baseline applies and then make a determination on the appropriateness/necessity of obtaining an independent assessment. Assessments of controls can be performed by contractor, government, or third parties, with third party verification considered the strongest. If independent assessment is required, include statement below. Thereafter, the Contractor, in coordination with the NIH shall conduct/assist in the assessment of the security controls and update the SAR at least annually.

   iii. Independent Assessment - due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The Contractor (and/or subcontractor) shall have an independent third-party validate the security and privacy controls in place for the system(s). The independent third party shall review and analyze the Security Authorization package, and report on technical, operational, and management level deficiencies as outlined in NIST SP 800-53. The Contractor shall address all "high" deficiencies before submitting the package to the Government for acceptance. All remaining deficiencies must be documented in a

system Plan of Actions and Milestones (POA&M).

iv. POA&M - due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The POA&M shall be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies. All high-risk weaknesses must be mitigated within 30 days and all medium weaknesses must be mitigated within 60 days from the date the weaknesses are formally identified and documented. The NIH will determine the risk rating of vulnerabilities. Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as documented in the SAR, shall be documented and tracked by the Contractor for mitigation in the POA&M document. Depending on the severity of the risks, NIH may require designated POAM weaknesses to be remediated before an ATO is issued. Thereafter, the POA&M shall be updated no less than quarterly.

c. Contingency Plan and Contingency Plan Test - due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The Contingency Plan must be developed in accordance with NIST SP 800-34, Contingency Planning Guide for Federal Information Systems, and be consistent with HHS and NIH policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, shall test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned and any action items that need to be addressed. Thereafter, the Contractor shall update and test the Contingency Plan at least annually.
E-Authentication Questionnaire - The contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04 and NIST SP 800-63, Rev. 2, Electronic Authentication Guidelines.

Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

d. POSITION SENSITIVITY DESIGNATIONS
All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this contract:

[ ] Level 6: Public Trust - High Risk. Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] Level 5: Public Trust - Moderate Risk. Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[X] Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

e. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12 Roster

i. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx .

ii. If the Contractor is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

iii. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

iv. The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

v. All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract. Contractors may begin work after the fingerprint check has been completed.

vi. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent

re-investigation may not be excusable in accordance with the FAR clause 52.249-14, Excusable Delays. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

vii. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).

viii. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

ix. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

x. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

f. CONTRACT INITIATION AND EXPIRATION

i. General Security Requirements- The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology and in accordance with the HHS Contract Closeout Guide (2012).
HHS EA requirements may be located here:
https://www.hhs.gov/ocio/ea/documents/proplans.html

ii. System Documentation- Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, Security Considerations in the System Development Life Cycle, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

iii. Sanitization of Government Files and Information- As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately

disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

iv. Notification- The Contractor (and/or any subcontractor) shall notify the CO and/or COR and system ISSO within fifteen days before an employee stops working under this contract.

v. Contractor Responsibilities Upon Physical Completion of the Contract- The contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or NIH policies.

vi. The Contractor (and/or any subcontractor) shall perform and document the actions identified in the NIH Contractor Employee Separation Checklist https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf when an employee terminates work under this contract within 2 days of the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.

g. Contractor Non-Disclosure Agreement (NDA)

Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the NIH non-disclosure agreement https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf as applicable. A copy of each signed and witnessed NDA shall be submitted to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

h. Vulnerability Scanning Reports

The Contractor shall report the results of the required monthly special vulnerability scans no later than 10 days following the end of each reporting period. If required monthly, this report may be included as part of the Technical Progress Report. Otherwise, this report shall be submitted under a separate cover on monthly basis.

i. Government Access for Security Assessment.

In addition to the Inspection Clause in the contract, the Contractor (and/or any subcontractor) shall afford the Government access to the Contractor's facilities, installations, operations, documentation, information systems, and personnel used in performance of this contract to the extent required to carry out a program of security assessment (to include vulnerability testing), investigation, and audit to safeguard against

threats and hazards to the confidentiality, integrity, and availability of federal data or to the protection of information systems operated on behalf of HHS, including but are not limited to:

i. At any tier handling or accessing information, consent to and allow the Government, or an independent third party working at the Government's direction, without notice at any time during a weekday during regular business hours contractor local time, to access contractor and subcontractor installations, facilities, infrastructure, data centers, equipment (including but not limited to all servers, computing devices, and portable media), operations, documentation (whether in electronic, paper, or other forms), databases, and personnel which are used in performance of the contract.
   The Government includes but is not limited to the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include but not be limited to such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.
ii. At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.
iii. Segregate Government protected information and metadata on the handling of Government protected information from other information. Commingling of information is prohibited. Inspectors, auditors, and investigators will not be precluded from having access to the sought information if sought information is commingled with other information.
iv. Cooperate with inspections, audits, investigations, and reviews.

5. Legacy System Security Plan

The Contractor shall submit a plan no later than 30 days following the award of the contract documenting their plan for bringing legacy systems, applications, and computers into compliance with NIST guidelines.

6. Section 508 Annual Report

   The contractor shall submit an annual Section 508 report in accordance with the schedule set forth by the Contracting Officer (CO)/Contracting Officer's Representative (COR). The Section 508 Report Template and Instructions for completing the report are available at: http://www.hhs.gov/web/508/contracting/technology/vendors.html under "Vendor Information and Documents."

7. Environment, Health and Safety

   EHS Program Description Document: Provide a summary of the EHS Program, scope/exclusions, approach, flow down of requirements, implementing process, program assessments, variance process, and appendices. Due within 3 months of contract award and annually thereafter.

8. Contracts and Administration

   a. Technology Transfer Agreements Report
      The Contractor shall maintain appropriate records of all its technology transfer activities. The Contractor shall forward reports of all records of its technology transfer activities in a manner and to the extent satisfactory to each of the Contracting Officer's Representatives (CORs) for Intellectual Property for review. Records which are not required to be part of this report would include those handled separately by the Government. However, said reports should include any other technology transfer-related agreements, such as Material Transfer Agreements (MTAs), Confidential Disclosure Agreements (CDAs), Contractor Collaborative Research and Development Agreements (cCRADAs), beta test agreements, collaboration agreements, software agreements, etc. In addition, the Contractor shall identify all subcontracts in which the Contractor included (after the Government provides notification of DEC and/or deviated clause approval) a clause which deviates from FAR clause 52.227-11, 52.227-14, and/or 52.227-17. The report shall include the subcontract number, name of subcontractor, name of program and requester for which the subcontract was prepared, reason for need to deviate, and an extract of the language from the subcontract in which the subcontractor has agreed to accept a future deviated clause, or, the actual deviated clause (or title of deviated clause) included in the subcontract. Reports shall be provided to the CORs for Intellectual Property on an annual basis with a due date of February 15th and cover the previous calendar year. Such reports shall be prepared in a format to be agreed upon between the Contractor and the COR for Intellectual Property, and in such a format which will serve to adequately inform DHHS of the Contractor's technology transfer activities.

b. Technology Transfer, Disposition of Funds (cCRADA)
Any funds received by the Contractor under a cCRADA, shall be reported to the Technology Transfer COR and the Contracting Officer within 30 days of receipt of such funds and used by the appropriate Contractor Research Laboratory in accordance with the terms of the cCRADA. A separate cost center itemizing costs expended shall be maintained for each cCRADA.

c. Technology Transfer, Royalty Income
Any royalty funds received by the Contractor, shall be reported to the Technology Transfer COR and Contracting Officer within 30 days of receipt of such funds and used in accordance with 15 U.S.C. 3710a.

d. Active CRADA Progress Report
The Contractor shall, within 30 calendar days following the end of each contract year, provide to the Technology Transfer COR and the Contracting Officer, a report on the progress of active Contractor CRADAs and a separate accounting of how CRADA funds were expended, in accordance with the format and content of the Cost Status Report required to be submitted by the Contractor as set forth elsewhere in this contract. In addition, the report shall provide licenses let, royalty funds collected, and a separate accounting of how such royalty funds were used. Financial reports shall be in accordance with the format and content of the Cost Status Report required to be submitted by the Contractor as set forth elsewhere in this contract.

e. Technology Transfer Plan
The Contractor is required to submit to the Technology Transfer COR and the Contracting Officer, annually, a technology transfer plan for conducting its technology transfer functions for the upcoming year. This plan is due annually, no later than January 15th each year.

9. Biennial Property Inventory

The Contractor is required to submit to the Property COR and Contracting Officer, a biennial inventory as set forth in the "HHS Contracting Guide for Contract of Government Property" and other periodic inventories as requested by the MOSB Property Administrator. The first biennial inventory shall be provided November 30, 2020 and shall be provided by November 30 every two years thereafter, assuming an option has been exercised allowing for submission. The inventory shall contain all Accountable Government Property.

10. Accountable Government Property List

By August 31st of each contract year, submit to the Property COR and Contracting Officer the accountable government property list covering all government furnished property and property acquired for use in the performance of this contract and all associated task orders, as provided

by the Government Property clause and the instructions contained in the "HHS Contracting Guide for Contract of Government Property" issued in 2007. This report is required to be submitted under this contract and must identify under which contract/task order the property was acquired. Submission of this list satisfies the Contracting Officer Authorization requirement for "sensitive items" under Article B.5.9 for the subsequent contract year.

11. List of Business Interests

    Within thirty (30) calendar days after contract award, the Contractor shall submit a complete listing of all businesses in which it has an ownership interest, including but not limited to affiliates and subsidiaries to the Contracting Officer. The Contractor shall update the list as variances in business interests occur and furnish one (1) copy to the Contracting Officer.

12. Report of Corporate Transactions/Activities

    The Contractor shall submit a report of all corporate transactions/activities pertaining to the contract effort on the IDIQ contract and in awarded task orders. Report is due as requested by the Contracting Officer.

13. Standard Process Listing

    The Contractor shall maintain an electronic copy of all Standard Processes (SPs) and provide a comprehensive listing to the Contracting Officer upon request. The list shall include SP number, name, a brief description, and date last updated.

14. Service Contract Report (SCR)

    In accordance with FAR clause 52.204-15, Service Contract Reporting Requirements for Indefinite Delivery Contracts (Jan 2014), the Contractor shall enter and submit the following Service Contract Report data elements into System for Award Management (SAM), with a copy to the Contracting Officer annually, by October 31st for services performed under this contract during the preceding Government fiscal year (October 1 - September 30). SCR data elements:
    a. Contract Number
    b. The total dollar amount invoiced for services performed during the previous Government fiscal year under the contract.
    c. Total number of Contractor direct labor hours expended on the services performed during the previous Government fiscal year.
    d. Data reported by first-tier subcontractors that have provided services under this contract, as applicable.
        i. First-tier Subcontract number (including subcontractor name and DUNS number)
        ii. The number of first-tier subcontractor direct-labor hours expended on the services performed during the previous Government fiscal year.

15. Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons

The Contractor shall comply with the reporting requirements of FAR clause 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons, and submit in https://www.sam.gov

16. Human Resources

a. Staffing Plan
Annually on August 26th, the Contractor shall submit to the Contracting Officer, a schedule including, but not limited to, the distribution/organization of all employees, including employee #, position title, grade/step, salary, actual cost per employee to the Government and date of eligibility for next increase.
b. Headcount Report
Monthly on the 28th, the Contractor shall submit to the Contracting Officer, a report of headcount by month and location.
c. Pre-Hire Listing
As required, the Contractor shall submit, to the Administrative Officers (AO), a report notifying AOs of the information required to enter Contractor new hires and transfers into NED system and lists the clearance levels required.
d. Position/Title Report
Annually on June 15th, the Contractor shall submit to the Contracting Officer, a report describing all Positions/Titles, education and experience requirements, and grade.
e. Recruitment Status Report
Monthly on the 28th, the Contractor shall submit, to the Contracting Officer, a report providing the status of recruitment and hiring of open requisitions/positions.
f. Bench Report
As requested, the Contractor shall submit, to the Contracting Officer, a report of employees applied to the Bench Program and the duration of time on the Bench Program.
g. Employee Distribution Across Task Order
Quarterly on 11/15, 02/15, 05/15, and 08/15, the Contractor shall submit, to the Contracting Officer, a report of FTE allocation by task order.
h. Discretionary Leave Report
Annually on August 26th, the Contractor shall submit a report to the Contracting Officer, a report on usage of Discretionary Leave and Unscheduled Closure Telework employee status. This report shall include: A breakdown of the total number of hours, per FTE, associated with each Discretionary Leave category, and a breakdown of the employee population, by tier, including the percentage of eligible employees designated as Tier II Non-Emergency Telework Employees.
i. Employee Roster
Monthly on the 28th, the Contractor shall submit, to the Contracting Officer, a list of all employees, contact information and security level.

17. Facilities, Maintenance and Engineering

a. Facilities Operations Manual (FOM)
   Within three (3) months of contract award, and annually thereafter, the Contractor shall submit to the Facilities Maintenance, and Engineering (FME) COR and the Contracting Officer, the FOM. Annual submissions shall contain revisions to the previous version and a conformed version.
b. Utility Meter Readings
   Monthly aligned with the utility billing periods, the Contractor shall submit, to the FME COR and the Contracting Officer, a record of steam, water, and electricity meter readings. The report shall include identification of each meter/location, current reading, date of reading, consumption for the month, and year to date consumption.

18. Financial Management

a. Advance Payment Monthly Reconciliation Report
   Monthly, the Contractor shall submit to the Financial Management COR and Contracting Officer, an advance payment monthly reconciliation report on the operations of the special bank account. This report shall include the special account balance sheet, summary of the account balance, and status by task order. The report shall be delivered on the 20th of each month.
b. Advance Payment Annual Analysis Report
   Annually, the Contractor shall submit to the Financial Management COR and Contracting Officer, an advance payment analysis report on the status of the special bank account. This report shall include updated working capital forecasting based on actual contract costs as well as an analysis of the account balance and need for advance payment to cover all projected working capital needs for the following year based on actual contract costs. The report shall be delivered annually on the 20th of May.

19. FFRDC Annual Report and Contractor Performance Status Report (CPSR)

a. The Contractor shall submit an Annual Report documenting the progress/results of the Contractor's technical and management efforts during each year of the contract. The reports shall comprehensively explain the work performed and shall contain, as a portion thereof, a one-page executive summary.
b. The Contractor shall submit the CPSR twice annually, mid-year and as an appendix to the Annual Report. The mid-year CPSR shall be due on June 15 and cover the period from the previous October 01 to March 31. The appendix to the Annual Report shall be due with the Annual Report on December 15 and cover the period from April 01 to September 30. The CPSR shall contain a 20-page summary of accomplishments. In addition, the CPSR shall contain Technical Goals & Objectives, Bibliography, and Operations Goals & Objectives and Metrics.

20. Miscellaneous Reports

The Contractor shall submit such other reports, in the time frames specified, pertaining to the contract effort as may be requested by the Contracting Officer or duly authorized representatives.

21. Reports shall be sent to the following addresses as specified:

Deliver to:	No. of Copies
FFRDC Contract Administration System https://fcas.nci.nih.gov	One (1) Electronic Copy

(Applicability specified at task order level)
In addition to the above, one electronic copy of the following reports shall be sent to: Gail Blaufarb, Team Leader, Technical Operations, Research Analysis and Evaluation Branch, Division of Extramural Activities, NCI, 6116 Executive Blvd., Room 8023, MS 8326, Bethesda, MD 20892 (for regular mail) or Rockville, MD 20852 (for hand carry), e-mail: blaufarg@mail.nih.gov:

- Annual & Final Inclusion Enrollment Reports (For NCI level of effort clinical research projects involving human subjects)

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor/FAR Clause 52.227-13, Patent Rights-Ownership by the Government *(or deviation thereof)* and including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The first annual utilization report shall be due on or before 05/20/2020. Thereafter, reports shall be due on or before the 10th working day following the reporting period. All reports shall be sent electronically to the Contracting Officer at FFRDC Contract Administration System https://fcas.nci.nih.gov.

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison

is required as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with the Contract, individual task orders, Government regulations, and/or Government specifications as applicable. At a minimum, all deliverables shall be marked with Contract number, Task Order number, and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

All packages, markings, and shipments must be in compliance with applicable federal and international regulations, including, but not limited to: Department of Transportation regulations, Export Administration Regulations (EAR), Federal Aviation Administration (FAA) regulations, International Air Transport Association (IATA) dangerous goods regulations, Hazardous Materials Regulations (49 CFR 171-180), and Occupational Safety and Health Standards (29 CFR 1910.1030).

Any additional packaging, marking, and shipping specifications shall be identified in each task order.

SECTION E - INSPECTION AND ACCEPTANCE

A. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of materials and services to be provided.

B. Inspection and acceptance will be performed as identified in the parent IDIQ Contract for contract-wide requirements and per task order for specific task order requirements.

   Inspection and acceptance for parent IDIQ Contract contract-wide requirements will be performed at:

   National Cancer Institute at Frederick
   FFRDC Contract Administration System
   https://fcas.nci.nih.gov

   Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

C. This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this

address: https://www.acquisition.gov/?q=browsefar .

FAR Clause **52.246-4, Inspection of Services - Fixed Price** (August 1996). **(APPLICABLE TO FIXED PRICE TASK ORDERS ONLY)**

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984). **(APPLICABLE TO COST REIMBURSEMENT TASK ORDERS ONLY)**

FAR Clause **52.246-7, Inspection of Research and Development - Fixed Price** (August 1996). **(APPLICABLE TO FIXED PRICE TASK ORDERS FOR RESEARCH AND DEVELOPMENT ONLY)**

FAR Clause **52.246-8, Inspection of Research and Development - Cost-Reimbursement** (May 2001). **(APPLICABLE TO COST REIMBURSEMENT TASK ORDERS FOR RESEARCH AND DEVELOPMENT ONLY)**

Alternate I (April 1984) is not applicable to this contract.

FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984). **(APPLICABLE TO COST REIMBURSEMENT, COMPLETION TYPE TASK ORDERS FOR RESEARCH AND DEVLOPMENT ONLY)**

FAR Clause **52.246-16, Responsibility for Supplies** (April 1984). **(APPLICABLE TO FIXED PRICE TASK ORDERS ONLY)**

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. ORDERING PERIOD

A. The ordering period of this contract shall be from June 26, 2019 through June 25, 2021.

B. If the Government exercises Options pursuant to the OPTION PROVISION Article in Section H of this contract, the ordering period will be extended as follows:

Option	Option Period
Option Period 1	June 26, 2020 - June 25, 2021
Option Period 2	June 26, 2021 - June 25, 2022
Option Period 3	June 26, 2022 - June 25, 2023

Option	Option Period
Option Period 4	June 26, 2023 - June 25, 2024

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of each task order and upon delivery and acceptance by the Contracting Officer, or the duly authorized Contracting Officer's Representative (COR), of the items in accordance with the stated delivery schedule of each task order. The items below are to be delivered on the parent IDIQ for all awarded task orders:

A. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract:

Item	Contract Article	Description	Delivery Schedule
1	C.2.B.1	Reporting of Financial Conflict of Interest (FCOI)	Due as FCOI arises
2	C.2.B.2	Report of USDA-Designated Biobased Products	Due annually on 10/31 and prior to the end of contract performance.
3	C.2.B.3	Source Code and Object Code	Due upon expiration date of each applicable task order
4	C.2.B.4.a	Security Assessment and Authorization (SA&A)	Due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO
5	C.2.B.4.b.i	System Security Plan (SSP)	Due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO
6	C.2.B.4.b.ii	Security Assessment Plan/Report (SAP/SAR)	Due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO
7	C.2.B.4.b.iii	Independent Assessment	Due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO
8	C.2.B.4.b.iv	POA&M	Due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO
9	C.2.B.4.c	Contingency Plan and Contingency Plan Test	Due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO
10	C.2.B.4.e	HSPD-12 Roster	Due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO

Item	Contract Article	Description	Delivery Schedule
11	C.2.B.4.f	Contract Initiation and Expiration Notification	Due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO
12	C.2.B.4.g	Contractor NDA	Due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO
13	C.2.B.4.h	Vulnerability Scanning Reports	Due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO
14	C.2.B.5	Legacy System Security Plan	Due 30 days after contract award
15	C.2.B.6	Section 508 Annual Report	Due annually in accordance with the schedule set forth by the Contracting Officer (CO)/Contracting Officer's Representative (COR)
16	C.2.B.7	EHS Program Description Document	Due within 3 months of contract award and annually thereafter
17	C.2.B.8.a	Technology Transfer Agreements Report	Due annually on 02/15
18	C.2.B.8.b	Technology Transfer, Disposition of Funds (cCRADA)	Due within 30 days of receipt of such funds
19	C.2.B.8.c	Technology Transfer, Royalty Income	Due within 30 days of receipt of such funds
20	C.2.B.8.d	Active CRADA Progress Report	Due annually 30 days after the end of the contract year
21	C.2.B.8.e	Technology Transfer Plan	Due annually no later than January 15th each year
22	C.2.B.9	Biennial Property Inventory	Due every two years on November 30, starting 11/30/20
23	C.2.B.10	Accountable Government Property List	Due annually on 08/31
26	C.2.B.11	List of Business Interests	Due within 30 days of contract award and updated as variances in business interests occurs
27	C.2.B.12	Reports of Corporate Transactions/Activities	As requested by the CO
28	C.2.B.13	Standard Process Listing	As requested by the CO
29	C.2.B.14	Service Contract Reporting	Due annually on 10/31 and prior to the end of contract performance
30	C.2.B.15	Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons	Due annually on 11/30 and prior to the end of contract performance
31	C.2.B.16.a	Staffing Plan	Due annually on 08/26
32	C.2.B.16.b	Headcount Report	Due monthly on the 28th of each month
33	C.2.B.16.c	Pre-Hire Listing	Submit as Pre-Hire requirement arises
34	C.2.B.16.d	Position/Title Report	Due annually on 6/15

Item	Contract Article	Description	Delivery Schedule
35	C.2.B.16.e	Recruitment Status Report	Due monthly on the 28th of each month
36	C.2.B.16.f	Bench Report	Submit as requested
37	C.2.B.16.g	Employee Distribution Across Task Order	Due quarterly on 11/15, 02/15, 05/15, and 08/15
38	C.2.B.16.h	Discretionary Leave Report	Due annually on 08/26
39	C.2.B.16.i	Employee Roster	Due monthly on the 28th of each month
40	C.2.B.17.a	FOM	Due within 3 months of contract award and annually thereafter
41	C.2.B.17.c	Utility Meter Readings	Due monthly to align with the utility billing periods
42	C.2.B.18.a	Advance Payment Monthly Reconciliation Report	Due monthly on the 20th of each month
43	C.2.B.18.b	Advance Payment Annual Analysis Report	Due annually on 05/20
44	C.2.B.19.a	FFRDC Annual Report	Due annually on 12/15, starting 12/15/20
45	C.2.B.19.b	CPSR	Due twice annually, on 06/15 (stand-alone) and 12/15 (appendix to FFRDC Annual Report)
46	C.2.B.20	Retirement Program Status Report	Due annually on 08/01
47	C.2.B.21	Miscellaneous Reports	Submit as requested
48	C.3	Annual Utilization Report	Due annually on 05/20
49	C.3	Final Invention Statement	Due on the end of contract performance
50	H.20.G	Monthly Summary of Sales	Due monthly within 10 days from the close of the reporting period
51	H.38.B.1	Individual Subcontract Reports	Due twice annually on 04/30 and 10/30. Final report due on the end of contract performance
52	H.38.B.2	Summary Subcontract Reports	Due annually on 10/30
53	H.47.F	Advance Copies of Press Releases	Submit prior to release
54	H.61.C	Plan for Phase-In, Phase-Out Operations	Due within 30 days after contract award to a successor Contractor

B. The above items shall be addressed and delivered to:

Addressee	**Deliverable Item No**
Contracting Officer and appropriate COR(s) via FFRDC Contract Administration System (FCAS), fcas.nci.nih.gov	14, 16-28, 31-32, 34-48, 51, 54-55
In accordance with COR direction	1, 3-13, 15, 33
Submitted via sam.gov	2, 29-30, 52-53

Addressee	Deliverable Item No
Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986) and the Contracting Officer via FCAS	49-50

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/?q=browsefar .

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) **(APPLICABLE TO FIXED PRICE TASK ORDERS ONLY)**

52.242-15, Stop Work Order (August 1989)
Alternate I (April 1984) is applicable to this contract. **(APPLICABLE TO COST REIMBURSEMENT TASK ORDERS ONLY)**

52.211-11, Liquidated Damages--Supplies, Services or Research and Development (September 2000). **(APPLICABLE TO FIXED PRICE TASK ORDERS ONLY)**

"(a) If the Contractor fails to deliver the supplies or perform the services within the time specified in this contract, the Contractor shall, in place of actual damages, pay to the Government liquidated damages of $*TBN** per calendar day of delay."

**Amount to be negotiated per fixed price task order awarded*

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVES (CORs)

The following Contracting Officer's Representatives (CORs) will represent the Government for the purpose of this contract:

COR	Area of Responsibility
[redacted]	FFRDC – Technical and Scientific Support
[redacted]	Financial Management
[redacted]	Facilities Maintenance, and Engineering (FME)
[redacted]	Environment, Health and Safety (EHS)

[redacted]	Information Systems and Technology
[redacted]	Technology Transfer/Intellectual Property
[redacted]	LBR Source Evaluation Groups

The CORs are responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract.

The Government may unilaterally change its COR designation(s).

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of Clause)

The following individuals are considered to be essential to the work being performed hereunder:

Name	Title
[redacted]	President/CEO
[redacted]	Chief Medical Officer
[redacted]	Chief Operating Officer

Name	Title
[redacted]	Chief Science Officer
[redacted]	Director, Project Management Operations Office
[redacted]	Directorate Head, Biopharmaceutical Development Program Directorate

ARTICLE G.3. TASK ORDER PROCEDURE

This contract provides for the issuance of Task Orders on a negotiated basis as follows:

A. General

Only the Contracting Officer may issue Task Orders to the Contractor, providing specific authorization or direction to perform work within the scope of the contract and as specified in the Statement of Work. Unless specifically authorized by the Contracting Officer, the Contractor shall not commence work until a fully executed Task Order has been awarded. The Contractor may incur costs under this contract in performance of task orders and task order modifications issued in accordance with this ARTICLE.

No other costs are authorized unless otherwise specified in the contract or expressly authorized by the Contracting Officer.

B. Requesting Task Order Proposals

A Task Order Request for Proposals (TORFP) will be prepared and issued by the Contracting Officer for each task order requirement.

Generally, the Task Order Request for Proposal (TORFP) will include but is not limited to the following:

1. Statement of Work;
2. Reporting Requirements and Deliverables;
3. Proposal Due Date and Location to Deliver Proposals;
4. Period of Performance of Task Order;
5. Anticipated type of Task Order;
6. Technical Proposal Instructions;
7. Business proposal Instructions; and,
8. Evaluation Factors for Award

All applicable contract clauses contained in this contract shall be incorporated in the TORFP and the resultant task order. If conflicts exist between the contract clauses and the information outlined in the task order, the contract language takes precedence over the information in the task order.

C. Evaluation and Award of Task Order Proposals

The Government will evaluate the Task Order proposals against the requirements of the TORFP. Specifically, the technical evaluation factors, cost/price, and any other factor specifically identified in the TORFP will be used for evaluation of each proposal. In addition, the TORFP will identify the basis for award. Generally, technical factors will be significantly more important than cost or price. However, each TORFP will specify how the award decision will be made.

Upon completion of evaluations, the Contracting Officer will issue a task order to the Contractor.

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT (APPLICABLE TO COST-REIMBURSEMENT TASK ORDERS ONLY)

A. Invoice Submission/Contract Financing Request and Contract Financial Reporting, NIH(RC)-4 for NIH Cost-Reimbursement Type Contracts are attached and made part of this contract. Invoices shall be submitted in accordance with Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

The following regarding invoice instructions and submission procedures is agreed and understood:

- Format: Contractor Format shall be used (NIH(RC)-4 variance)
- Frequency/Terms: Invoicing shall be every 4 weeks with NET 30 calendar day payment terms for all task orders
- Direct Labor: Additional breakdown for labor (employee unique identifier and salary or hourly rate) shall be provided on all invoices
- Accountable Government Property: “capital equipment” definition applies (NIH(RC)-4 variance)

1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.

    a. The Contractor shall submit invoice to the National Institutes of Health (NIH)/Office of Financial Management (OFM) via email at invoicing@nih.gov with a copy to the approving official, as directed below. The Contractor must follow step-by-step instructions as stated in the NIH/OFM Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract. The invoice shall be transmitted as an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only **one** invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

    For inquiries regarding the status of invoices, contact OFM Customer Service via email at ofm_customer_service@incontactemail.com or via phone at 301-496-6088. To send your

inquiries via other available communication methods refer to the OFM Customer Service website at https://ofm.od.nih.gov/Pages/Customer-Service.aspx.

Note: The OFM Customer Service is open Eastern Standard Time Monday – Friday from 8:30 a.m. to 5:00 p.m. and is closed between 12:00 p.m. to 1:00 p.m.

b. One courtesy copy of the original invoice shall be submitted electronically as follows:
    i. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
    ii. **Save** the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Company Name_Invoice 123456") [Note: Please do not use special characters such as (#, $, %,*, &, !) when saving your attachment. Only the underscore symbol (_) is permitted.]
    iii. **Transmit** the saved single attachment electronically to the appropriate branch's Central Point of Distribution. For the purpose of this contract and all task orders awarded hereunder, the Central Point of Distribution is: FFRDC Contract Administration System https://fcas.nci.nih.gov.

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

    a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute.

    b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in SAM. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [*Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    d. Invoice Matching Option. This contract requires a two-way match.

e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

f. The Contract Title is: The NCI FFRDC Contract

g. Contract Line Items as follows:

PRISM Line Item #	Line Item Description/Project ID	IC	CAN	CAN Label	Amount	End Date of Funds Availability

3. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

4. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

ARTICLE G.5. INVOICE SUBMISSION (APPLICABLE TO FIXED PRICE TASK ORDERS ONLY)

A. Invoice Instructions for NIH Fixed-Price Type Contracts, NIH(RC)-2, are attached and made part of this contract. Invoices shall be submitted in accordance with Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.

a. The Contractor shall submit invoice to the National Institutes of Health (NIH)/Office of Financial Management (OFM) via email at invoicing@nih.gov with a copy to the approving official, as directed below. The Contractor must follow step-by-step instructions as stated in the NIH/OFM Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract. The invoice shall be transmitted as

an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only **one** invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

For inquiries regarding the status of invoices, contact OFM Customer Service via email at ofm_customer_service@incontactemail.com or via phone at 301-496-6088. To send your inquiries via other available communication methods refer to the OFM Customer Service website at https://ofm.od.nih.gov/Pages/Customer-Service.aspx.

Note: The OFM Customer Service is open Eastern Standard Time Monday – Friday from 8:30 a.m. to 5:00 p.m. and is closed between 12:00 p.m. to 1:00 p.m.

b. One courtesy copy of the original invoice shall be submitted electronically as follows:
    i. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
    ii. **Save** the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Contractor Name_Invoice 123456") [Note: Please do not use special characters such as (#, $, %,*, &, !) when saving your attachment. Only the underscore symbol (_) is permitted.]
    iii. **Transmit** the saved single attachment electronially to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is https://fcas.nci.nih.gov.

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

    a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute.

    b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in SAM. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on

the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [*Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

d. Invoice Matching Option. This contract requires a two-way match.

e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

f. The Contract Title is: The NCI FFRDC Contract

g. Contract Line Items as follows:

PRISM Line Item #	Line Item Description/Project ID	IC	CAN	CAN Label	Amount	End Date of Funds Availability

3. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

4. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

   "I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."
   Note: This subparagraph applies to Fixed Price Level of Effort Task Orders Only.

ARTICLE G.6. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

A. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
B. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

C. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.
(End of Clause)

ARTICLE G.7. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6011 EXECUTIVE BLVD, ROOM 549C, MSC-7663
BETHESDA MD 20892-7663

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.8. GOVERNMENT PROPERTY

A. In addition to the requirements of FAR clause 52.245-1, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated into this contract by reference. This document can be accessed at:
http://oamp.od.nih.gov/sites/default/files/appendix_q_hhs_contracting_guide.pdf .
Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Requests for information regarding property under this contract should be directed to the Contracting Officer.

B. Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated in this contract in paragraph A above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

C. Property Acquired Under Predecessor Contract - Schedule II-A
Pursuant to FAR clause 52.245-1, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor is hereby authorized to retain custody of all Government Property acquired or furnished under predecessor Contract No. HHSN261200800001E/HHSN261201500003I for use in direct performance of this contract. Accountability for the items is hereby authorized to be transferred to

this contract from the predecessor contract. Upon completion of each contract, the Contractor agrees to furnish to the Contracting Officer, without delay, the inventory schedule covering all Government Property furnished or acquired for use in the performance of the predecessor contract as provided by FAR clause 52.245-1, GOVERNMENT PROPERTY, of that contract and the instructions contained in HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property." Schedule II-A is included as an attachment in SECTION J of this contract.

ARTICLE G.9. ON-SITE CONTRACTOR ACCESS TO GOVERNMENT PROPERTY

The Contractor shall be held responsible for Government Property, regardless of dollar value, when:

A. The contract requires contractor personnel to be located on a Government site or installation;
B. The property utilized by contractor personnel is incidental to the place of performance; and,
C. The property used by the contractor remains accountable to the Government ***Responsibility*** includes physical presence, proper use and handling, normal maintenance, and reporting loss, damage or destruction.

Responsibility for government property shared by two or more contractors or located in space shared by two or more contractors, shall be determined and documented by the contractors involved. In cases where the parties cannot reach agreement on shared responsibility, the matter will be referred to the NIH Property Officer for resolution.

ARTICLE G.10. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

A. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract and each Task Order in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared semi-annually on March 31st and September 30th.

Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted sixty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

B. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address: http://www.cpars.gov

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

A. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.
B. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.
C. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP Website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).
D. If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

(End of clause)

ARTICLE H.2. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.3. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by NCI , written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer 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. The human subject certification can be met by submission of the Contractor's 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).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, 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 research.

ARTICLE H.4. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html .

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.5. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring Plan shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.6. GOOD CLINICAL PRACTICE TRAINING FOR NIH AWARDEES INVOLVED IN NIH-FUNDED CLINICAL TRIALS

All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2). GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. GCP training should be refreshed at least every three years to remain current with regulations, standards and guidelines. The Contractor shall provide completion of training documentation to the Contracting Officer's Representative (COR).

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical Trial Staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

ARTICLE H.7. CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION

The Contractor conducting clinical trials, funded wholly or partially through the NIH extramural and intramural programs, shall ensure that its NIH-funded clinical trials are registered at, and summary results information is submitted to, www.clinicaltrials.gov for public posting. See NIH Guide Notice NOT-OD-16-149 dated September 16, 2016.

All NIH-funded clinical trials shall be registered and results information submitted to www.clinicaltrials.gov regardless of study phase, type of intervention, or whether they are subject to the regulation 42 CFR Part 11. Clinical trials subject to the regulation are called "applicable clinical trials."

The Contractor must submit a plan with its proposal to meet the regulatory requirements of the dissemination of information of NIH-funded Clinical Trials. The Contractor and investigators are required to comply with all terms and conditions of award, including following their acceptable plan for the dissemination of NIH-funded clinical trial information.

The Contractor must register all NIH-funded clinical trials in www.clinicaltrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of a new use is being sought. The Contractor shall include the trial registration number (NCT number) in the Technical Progress Report covering the period in which registration occurred, and as a standalone notification to the Contracting Officer within ten (10) calendar days of the registration. Each NIH-funded clinical trial must have only one entry in ClinicalTrials.gov that contains its registration and results information

The Contractor shall include a specific statement in all informed consent documents relating to posting of clinical trials information to www.clinicaltrials.gov . The responsibilities of the Contractor will fall within one of the following three categories:

A. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the Contractor is the responsible party, the Contractor will ensure that all regulatory requirements are met.
B. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the Contractor is not the responsible party, the Contractor will coordinate with the responsible party to ensure that all regulatory requirements are met.
C. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the Contractor will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

Failure to comply with the terms and conditions of the award may provide a basis for enforcement actions. Identifying clinical trial record as non-compliant in ClinicalTrials.gov may lead to termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 USC 282(j) and 42 CFR Part 11 may also lead to the actions described in 42 CFR 11.66.

The Contracting Officer may take one or more of the following enforcement actions, if the Contractor fails to provide evidence of compliance within 30 days.

D. Temporary withhold payments pending correction of the deficiency;
E. Disallow all or part of the cost of the activity or action not in compliance;
F. Wholly or partly suspend or terminate the contract award;
G. Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding regulations at 2 CFR part 376;
H. Withhold further awards for the project and program;
I. Take other remedies that may be legally available.

ARTICLE H.8. CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION PLAN

The special terms and conditions in the Contract Award that include a clinical trial:

A. The clinical trial(s) supported by this award is subject to the plan dated *TBD* submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan must state that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant. The plan also must state that primary summary results shall be reported in ClinicalTrials.gov, including adverse event information, not later than one year after the primary completion date of the trial. The reporting of summary results is required by this term of award.

B. This award is subject to reporting requirements with each submission of the annual report. Contractor shall agree to the following annual certification. By affirming this annual certification:

The Contractor hereby certifies that all investigators conducting NIH-funded clinical trials under the NIH contract number 75N91019D00024 are in compliance with the Contractor's plan addressing compliance with the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded wholly or partially under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Primary summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the primary completion date of the trial.

ARTICLE H.9. CERTIFICATE OF CONFIDENTIALITY

Section 2012 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions governing the authority of the Secretary of Health and Human Services (Secretary) to protect the privacy of individuals who are the subjects of research, including significant amendments to the previous statutory authority for such protections, under subsection 301(d) of the Public Health Service Act.

Effective October 1, 2017, all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of the NIH Policy for Issuing Certificate of Confidentiality (CoC) NOT-OD-17-109, the Contractor shall protect the privacy of individuals who are subjects of such research in accordance

with subsection 301(d) of the Public Health Service Act as a term and condition of the contract. The certificate will not be issued as a separate document.

NIH considers research in which identifiable, sensitive information is collected or used, to include:

A. Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research (except for human subjects' research that is determined to be exempt from all or some of the requirements of 45 CFR 46) if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
B. Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
C. Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
D. Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

The Contractor shall not:

E. Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
F. Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

The Contractor is permitted to disclose only in below circumstances. The Contractor shall notify the CO minimum ten (10) calendar days prior to disclosure.

G. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
H. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
I. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

J. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

In accordance with 45 CFR Part 75.303(a), the contractor shall maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal Statutes and regulations.

The recipient of CoCs shall ensure that any company/institution/individual not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate is subject to the requirements of subsection 301(d) of the Public Health Service Act. The Contractor shall ensure that Subcontractors who receive funds to carry out part of the Federal award are subject to subsection 301(d) of the Public Health Service Act and the NIH Policy for Issuing CoC.

ARTICLE H.10. SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For Institutional Review Board (IRB), the Contractor shall use the single Institutional Review Board (sIRB) of record for multi-site research. All domestic sites participating in multi-site studies involving a non-exempt human subjects research funded wholly or partially by the National Institutes of Health (NIH) shall use a sIRB to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46 and the NIH Policy on the Use of Single Institutional Review Board for Multi-Site Research . Any IRB serving as the sIRB of record for NIH funded research shall be registered with the HHS Office for Human Research Protections (OHRP) and shall have membership sufficient to adequately review the proposed study.

The Contractor shall provide to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 certifying IRB review and approval of the research that encompasses all sites of performance.

This paragraph applies only if the Government provided a sIRB through a separate entity as stated in section- C. When the Government provided sIRB through a separate entity, the Contractor agrees to use of the sIRB. The Contractor shall provide to the Contracting Officer sIRB information and data in a timely manner as necessary to meet the policy and/or regulatory requirements of the Protection of Human Subjects at 45 CFR Part 46.

Exceptions to the NIH Single IRB Policy

The Contractor may request an exception in the following instances:

A. Sites for which Federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions);
B. *Other exceptions*, to be determined by NIH if there is a compelling justification; and
C. Time Limited Exception: ancillary studies to ongoing research without a sIRB- new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use a sIRB of record until the parent study is expected to comply with the sIRB policy.

Policy-based exceptions and time limited exceptions are automatically granted when identified in the sIRB Plan.

Other exceptions must be reviewed by NIH sIRB Exceptions Review Committee (ERC) and are expected to be granted rarely. *Other exceptions* when Offeror believes that one or more research sites should be exempt from use of the single IRB of record to conduct local IRB review based on compelling justification-

D. Offerors should request an exception in the sIRB plan attachment within the contract proposal (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form).
E. Offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the sites(s).
F. Offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the sIRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).
   - For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.
G. Note that the proposed budget in the proposal must reflect all necessary sIRB costs without an approved *other exception.* The Offerors should not assume that an *Other Exception* will be granted when considering what sIRB costs to include in the budget.

Post-Award Exception Requests

For any post-award changes that necessitate an exception request, such as the addition of a new domestic site that may be unable to use the sIRB Contractor shall contact their Contracting Officer (CO). For policy-based exceptions, the Contractor shall provide the appropriate citation to verify the requirement for local IRB review for the newly added site(s) to the CO. For *other exceptions*, the Contractor shall provide compelling justification to the CO to be reviewed by the NIH Exceptions Review Committee (ERC) (see **Steps to Request an Other Exception to the sIRB Policy** above). For time limited exceptions, Contractor shall provide the parent contract number to the CO. For time limited exceptions, Contractor shall provide the parent contract number to the CO.

Notice of Approval or Disapproval of *Other Exception* Requests

The sIRB exception requests will be considered after peer review for proposals in the competitive range. The decision of NIH ERC is final. Offerors will be notified of the final decision by their CO prior to award. Approved exceptions will be incorporated as a term and condition in the contract award. Also, any exception requests submitted after award must be submitted to the CO and reviewed by the NIH ERC. No further revisions of the exception request will be accepted.

The award budget may need to be adjusted if an exception is granted.

ARTICLE H.11. PLAN FOR SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For this multi-site study, the ___ (contractor/each contractor) agrees to adhere to the NIH sIRB policy, and the ___ (IRB Name) IRB shall serve as the single IRB of record. All participating sites have agreed to rely on the ___ (IRB Name) IRB, and a written authorization/reliance agreement shall be developed. Any additional sites added after contract award shall also agree to rely on this study's single IRB of record. Communication plans for interactions between the sIRB and participating sites shall be described in the authorization/reliance agreement. All participating sites shall, prior to initiating the study, sign the authorization/reliance agreement that shall clarify the roles and responsibilities of the sIRB and participating sites. The ___ (Contractor Name/Name of the Coordinating Center or Contract Research Organization (CRO)/Names of Contractor's Lead Person and Alternate Person) shall maintain records of the authorization/reliance agreements, including the communication plans. The approved sIRB plan will be incorporated as a term and condition of the award. Any updates/changes to the plan shall be provided to the Contracting Officer's Representative with a copy submitted to the Contracting Officer within 30 calendar days.

Exceptions to the Single IRB Plan

The Contractor may request an exception to the sIRB plan under the following instances:

A. Sites for which federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions)
B. *Review by a single IRB of record will not be possible for (**sites)** because of federal/state/tribal law, regulation, or policy (**provide specific citation(s))***
C. *Other exceptions*, to be determined by NIH if there is a compelling justification
D. *Review by a single IRB of record will not be possible for (**this contractor)** because of (**provide compelling justification and rationale why local IRB is uniquely qualified to be the reviewing IRB for the specific site(s**)).*
E. Time Limited Exceptions: New multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use the sIRB of record until the parent study is expected to comply with the sIRB policy.

*Review by a single IRB of record will not be possible for (**sites)** because of ongoing multi-site parent study (**provide parent contract number)**.*

ARTICLE H.12. INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research in accord with Public Health Service Act sec. 4928 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except

when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended November 2017," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm .

The Contractor must submit the results of valid analyses by sex/gender and race/ethnicity to Clinicaltrials.gov for all NIH-conducted or supported applicable NIH-defined Phase III clinical trials. This requirement does not apply to NIH-defined Phase III trials not considered to applicable clinical trials under 42 CFR Part 11. The Contractor must report applicable NIH-defined Phase III clinical trials involving research subjects of all ages, including foreign awards and domestic awards with a foreign component. The Contractor must specify outcomes on sex/gender and race/ethnicity, as required based on prior evidence, and as explained in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

Note: Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information, including the results of the valid analyses by sex/gender and race/ethnicity, from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of new use is being sought.

ARTICLE H.13. INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. The NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accordance with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects.

Effective on all solicitations issued on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

The Contractor must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. The Contractor must provide a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the

scientific question proposed. If individuals will be excluded from the research based on age, the contractor must provide acceptable justification for the exclusion.

The Contractor must submit cumulative data as prescribed in the Age Enrollment Report template on participant age at enrollment in monthly progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided in progress reports.

ARTICLE H.14. POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV

The Revised Common Rule sections 46.102(b) and 46.116(h) requires Contractors to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database ClinicalTrials.gov . Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to Regulations.gov . The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit. The Contracting Officer (CO) and/or Contracting Officer's Representative (COR) may permit or require redactions as appropriate.

ARTICLE H.15. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf , Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

A. the registration of certain "applicable clinical trials" (see Definitions at: http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
B. the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

In addition, the Contractor shall notify the FFRDC-Technical and Scientific COR, with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand-alone notification.

The Government is the Sponsor, therefore the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov).Additional information is available at: http://prsinfo.clinicaltrials.gov

ARTICLE H.16. HIV ANTIRETROVIRAL TREATMENT TRIALS

The Contractor shall work with the host countries' authorities and other stakeholders in accordance with the approved plan to develop sources to provide HIV antiretroviral treatment to participants of the trials contracted for under this contract after the participants' completion of the trial.

ARTICLE H.17. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.18. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of 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).

ARTICLE H.19. RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (Including Human Gene Transfer Research)

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance

with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) available at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines). All NIH-funded projects abroad that include recombinant or synthetic nucleic acid molecules must also comply with the *NIH Guidelines*.

The *NIH Guidelines* stipulate biosafety and containment measures for recombinant or synthetic nucleic acid research, which is defined in the *NIH Guidelines* as research with (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The *NIH Guidelines* apply to both basic and clinical research. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the *NIH Guidelines*.

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the Contracting Officer to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an Institutional Biosafety Committee (IBC) registered with the NIH Office of Science Policy that complies with the requirements of the *NIH Guidelines*. Further information about compliance with the *NIH Guidelines* can be found on the NIH Office of Science Policy website available at: http://osp.od.nih.gov /.

ARTICLE H.20. REMITTANCE PROCEDURES FOR SALE OF RESEARCH SUBSTANCES AND LIVING ORGANISMS

A. The Contractor shall make available to individuals and entities, for biomedical and behavioral research, research substances and/or living organisms under the terms and conditions specified below and in Section C, Statement of Work, of this contract.

B. The Contractor shall bill recipients directly for the research substances and/or living organisms provided, including any shipping and handling costs, which shall be itemized separately on the recipient's invoice. The prices charged for research substances and/or living organisms shall be as specified in the price list, which is included as an attachment in Section J of this contract. Under no circumstances shall the Contractor bill prices other than those included in the price list unless directed to do so by the Contracting Officer or his/her designated representative. The Government, without the concurrence of the Contractor, may revise the price of the research substances and/or living organisms being made available. The Contracting Officer or his/her designated representative may direct the Contractor to make the research substances and/or living organisms available free of charge to recipients, including any shipping and handling costs.

C. The Contractor shall include with each shipment/transfer of research substances and/or living organisms to recipients an invoice substantially the same as the Sample Recipient Invoice, which is included as an attachment in Section J of this contract, and instruct the recipients how and when to

make payments.

D. The Contractor shall assign a unique invoice number to each invoice and instruct recipients to remit payment to the Contractor in U.S. dollars by check or other method acceptable to the Contractor within 15 calendar days from the date of the invoice. All payments shall be made payable to the Contractor.

E. The Contractor shall inform the recipients of the research substances and/or living organisms prior to shipment/transfer that: 1) such research materials are not returnable and the costs associated with providing them, including shipping and handling, are not refundable; and 2) failure to pay an invoice may result in future purchase requests being denied. The Contractor shall contact the Contracting Officer and his/her designated representative immediately if there are any issues with the research substances and/or living organisms provided to the recipients.

F. Shipping and handling costs are defined as follows: 1) shipping costs are costs charged for delivering the research substances and/or living organisms to the recipient, including insurance, if required; and 2) handling costs are the costs charged for preparing the research substances and/or living organisms for shipment/transfer, including labor, packaging, and invoicing. Excessive shipping and handling charges are to be avoided. Establishment of flat rate shipping and handling charges is encouraged; however, such charges must be approved in advance by the Contracting Officer or his/her designated representative.

G. The Contractor shall keep an accurate account of all sales of research substances and/or living organisms on a calendar month basis and report the following information to the Government: 1) recipient's name, address, and contact information; 2) quantity; 3) item shipped/transferred; 4) unit price; 5) shipping and handling charges; 6) total charges; 7) shipment/transfer date; 8) invoice number; and 9) payment due date. This information shall be reported on the form, Monthly Summary of Sales, which is included as an attachment in Section J of this contract, and submitted to the Government in accordance with the delivery schedule in Section F of this contract.

H. Upon receipt by the Government of the Monthly Summary of Sales, the Government will provide the Contractor with an invoice number needed to process payments through the U.S. Department of Treasury's government-wide collection portal, Pay.gov. Within 30 calendar days of receipt of the invoice number from the Government, the Contractor shall submit payment to the Government through Pay.gov for the research substances and/or living organisms associated with the invoice number received from the Government. Before submitting payment through Pay.gov, the Contractor shall reconcile the sales of research substances and/or living organisms reported on the Monthly Summary of Sales with the payment to be submitted to the Government.

For assistance with Pay.gov, reference the NIH Pay.gov User Guide included as an attachment in Section J of this contract. For further assistance, contact ncisresearchsubstances@mail.nih.gov.

I. Examination of costs and transaction records related to the sale of research substances and/or living organisms shall be subject to the terms and conditions of this contract, including FAR Clause 52.215-2, Audit and Records—Negotiation, and its applicable Alternates.

ARTICLE H.21. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103 , "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102 , "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research , whether preclinical or otherwise, as appropriate. More information is available at http://grants.nih.gov/reproducibility/index.htm , including FAQs and a General Policy Overview.

ARTICLE H.22. DATA SHARING IN GENOME-WIDE ASSOCIATION STUDIES (GWAS)

The Contractor shall submit and certify data obtained in the genome-wide association study to the NIH GWAS data repository in accordance with the NIH "Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)" located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html . All data and information shall be submitted to a high security network within the National Center for Biotechnology Information (NCBI), National Library of Medicine, through a secure transmission process. Data submitted to the database for genotypes and phenotypes (dbGaP) shall include the following basic study information:

A. the protocol,
B. questionnaires,
C. study manuals,
D. variables measured, and
E. other supporting documentation

The curated and coded phenotype, exposure, genotype, and pedigree data, as appropriate, should be submitted to the NIH GWAS data repository as soon as quality control procedures have been completed by the Contractor. Information on submitting data to dbGaP is available at: http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/GetPdf.cgi?document_name=HowToSubmit.pdf . Additional information about GWAS can be found at: http://gwas.nih.gov .

ARTICLE H.23. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting

from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html and http://publicaccess.nih.gov.

ARTICLE H.24. DUAL USE RESEARCH OF CONCERN

The contractor shall comply with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) or "DURC policy". The responsibilities of the contractor include but are not limited to:

A. Establishing internal policies and practices that provide for the identification and effective oversight of DURC;
B. Establishing an institutional review entity (IRE);
C. Ensuring that laboratory personnel conducting research have received education and training;
D. Maintaining records of institutional DURC reviews and completed risk mitigation plans related to research conducted under this contract, for the term of the contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation;
E. Promptly providing records upon request by the U.S. Government, of institutional DURC reviews and completed risk mitigation plans related to research conducted under this contract;
F. Obtaining pre-approval from the Contracting Officer's Representative for all communications with third-parties, involving DURC funded by this contract, and;
G. Obtaining pre-approval from the Contracting Officer for subcontracts, subgrants, consultant agreements, or any other subaward involving research subject to the DURC policy and funded by this contract. The contractor shall ensure that the substantive requirements of this article are included in any such agreements.

Non-compliance with the DURC policy or with this article may result in suspension, debarment or termination for default.

ARTICLE H.25. NEEDLE EXCHANGE, HHSAR 352.270-12 (December 2015)

The Contractor shall not use any funds obligated under this contract to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.
(End of clause)

ARTICLE H.26. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed

with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.27. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

A. The Contractor shall not use any funds obligated under this contract for any abortion.
B. The Contractor shall not use any funds obligated under this contract for the following:
    1. The creation of a human embryo or embryos for research purposes; or
    2. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
C. The term ``human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.
D. The Contractor shall not use any Federal funds for the cloning of human beings.

(End of clause)

ARTICLE H.28. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

ARTICLE H.29. PRIVACY ACT, HHSAR 352.224-70 (December 2015)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in CFR 45 part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor

is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.
(End of clause)

ARTICLE H.30. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

A. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor 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 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.
B. The Contractor 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 2.11, or from a source that is exempt from licensing under those sections.
C. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) 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 govern.
D. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor 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. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov ; Web site: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare).

(End of clause)

ARTICLE H.31. 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 (PHS Policy). The PHS Policy can be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR) dated 07/13/2017, which is incorporated by reference.

ARTICLE H.32. INTRODUCTION OF RODENTS AND RODENT PRODUCTS (Applicable to related activities at the NCI-Bethesda Campus only)

No rodent or rodent product shall be delivered into the NIH environment directly, or through collaborative research or holding facilities under contract to NIH except by permit. Direct shipments to NIH from a Division of Veterinary Resources (DVR), Office of Research Services (ORS) approved source will be considered exempt. Non-exempt sources must be approved by permit issued through the DVR, ORS. The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted by facsimile not less than 30 days prior (60 days in situations where quarantine is likely) to shipping date to: NIH Division of Veterinary Resources (DVR), Office of Research Services (ORS), Building 14G, Service Rd. South, Room 102, BETHESDA MD 20892-5210, (301)496-2527, FAX: (301) 402-0352.

ARTICLE H.33. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor 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," located at the following URL:

http://oma.od1.nih.gov/manualchapters/intramural/3044-2/

ARTICLE H.34. OMB CLEARANCE

In accordance with HHSAR 352.211-3, Paperwork Reduction Act, which is incorporated by reference in Section I.3 below, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Representative (COR) and the Contracting Officer has issued written approval to proceed.

ARTICLE H.35. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.36. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.37. OPTION PROVISION – ORDERING PERIOD

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period as set forth Sections B and F of the contract. Pursuant to FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional option periods. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the ordering period shall be increased as set forth in Ordering Period Article in SECTION F of this contract.

Task order specific option provisions will be specified in task orders as applicable.

ARTICLE H.38. SUBCONTRACTING PROVISIONS

A. **Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated June 26, 2019 is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

B. **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov :

1. Individual Subcontract Reports (ISR)

   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:
   April 30th; October 30th; Expiration Date of Contract

2. Summary Subcontract Report (SSR)

   Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:
   October 30th
   For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes to the following address: *scott.keasey@nih.gov*

ARTICLE H.39. HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

ARTICLE H.39.1. INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

(If any part of this article cannot be met, the contractor shall receive approval for an exception from the FFRDC CO, FFRDC IT COR and NCI CIO (or other IC CIO as appropriate) prior to taking any action.)

A. Baseline Security Requirements
   1. **Applicability-** The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:
      a. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.
      b. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.
   2. **Safeguarding Information and Information Systems-** In accordance with the Federal Information Processing Standards Publication (FIPS)199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall:
      a. Protect government information and information systems in order to ensure:
         - **Confidentiality** , which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
         - **Integrity** , which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
         - **Availability** , which means ensuring timely and reliable access to and use of information.

b. Provide security for any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor on behalf of HHS regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, **within one (1) hour or less** , bring the situation to the attention of the other party.

c. Adopt and implement the policies, procedures, controls, and standards required by the HHS Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the HHS Information Security Program security requirements, outlined in the HHS Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing fisma@hhs.gov .

d. Comply with the Privacy Act requirements.

3. **Information Security Categorization-** In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Contractor Non-Disclosure Agreement and based on information provided by the ISSO, CISO, or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Confidentiality:	[ ] Low	[X] Moderate	[ ] High
Integrity:	[ ] Low	[X] Moderate	[ ] High
Availability:	[ ] Low	[X] Moderate	[ ] High
Overall Risk Level:	[ ] Low	[X] Moderate	[ ] High

Based on information provided by the ISSO, Privacy Office, system/data owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:

[ ] No PII [X] Yes PII

Personally Identifiable Information (PII). Per the Office of Management and Budget (OMB) Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: social security number, date and place of birth, mother's maiden name, biometric records, etc.

PII Confidentiality Impact Level has been determined to be: [ ] Low [X] Moderate [ ] High

4. **Controlled Unclassified Information (CUI)-** CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "handling"

refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

a. Marked appropriately;
b. Disclosed to authorized personnel on a Need-To-Know basis;
c. Protected in accordance with NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and
d. Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

5. **Protection of Sensitive Information-** For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, Protection of Sensitive Agency Information by securing it with a FIPS 140-2 validated solution.
6. **Confidentiality and Nondisclosure of Information-** Any information provided to the contractor (and/or any subcontractor) by HHS or collected by the contractor on behalf of HHS shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any HHS records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

   The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and NIH policies. Unauthorized disclosure of information will be subject to the HHS/NIH sanction policies and/or governed by the following laws and regulations:

   a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
   b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
   c. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

   Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf . A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

7. **Internet Protocol Version 6 (IPv6)-** All procurements using Internet Protocol shall comply with OMB Memorandum M-05-22, Transition Planning for Internet Protocol Version 6 (IPv6).
8. **Government Websites-** All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.
9. **Contract Documentation-** The Contractor shall use provided templates, policies, forms and other agency documents provided by the Contracting Officer and the Contracting Officer's Representative to comply with contract deliverables as appropriate.
10. **Standard for Encryption-** The Contractor (and/or any subcontractor) shall:
    a. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.
    b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.
    c. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and NIH-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
    d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative within ***15 days*** of the validation .
    e. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys shall be provided to the COR upon request and at the conclusion of the contract.
11. **Contractor Non-Disclosure Agreement (NDA)-** Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the NIH non-disclosure agreement https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf , as applicable. A copy of each signed and witnessed NDA shall be submitted to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.
12. **Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)-** The Contractor shall assist the NIH Office of the Senior Official for Privacy (SOP) or designee with conducting a PTA for the information system and/or information handled under this contract to determine whether or not a full PIA needs to be completed. The NIH PIA guide is located at https://oma.od.nih.gov/forms/Privacy%20Documents/Documents/NIH%20PIA%20Guide.pdf .

a. If the results of the PTA show that a full PIA is needed, the Contractor shall assist the OpDiv SOP or designee with completing a PIA for the system or information within ***60 days*** after completion of the PTA and in accordance with HHS policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.
b. The Contractor shall assist the NIH Office of the SOP or designee in reviewing the PIA at least every three years throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

B. TRAINING

1. **Mandatory Training for All Contractor Staff-** All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/NIH Contractor Information Security Awareness, Privacy, and Records Management training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, the employees shall complete NIH Information Security Awareness, Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS training policies.
2. **Role-based Training-** All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training annually commensurate with their role and responsibilities in accordance with HHS policy and the HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum. Read further guidance about the NIH Role-based Training https://wiki.ocio.nih.gov/wiki/index.php/Role-Based_Training_Guidance
3. **Training Records-** The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall be provided to the CO and/or COR within 30 days after contract award and ***annually*** thereafter or upon request.

C. RULES OF BEHAVIOR

1. The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior, and comply with the NIH Information Technology General Rules of Behavior https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH%20IT%20General%20Rules%20of%20Behavior%20v2.0.pdf#search=general%20rules%20of%20behavior , which are contained in the NIH Information Security Awareness Training Course http://irtsectraining.nih.gov
2. All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least annually thereafter, which may be done as part of annual NIH Information Security Awareness Training. If the training is provided by the contractor, the signed Rules of Behavior must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

D. INCIDENT RESPONSE

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within 24 hours, whether the response is positive or negative.

FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII".

In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) shall:

1. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
2. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals in accordance with https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/index.aspx
3. Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) via email at IRT@mail.nih.gov , COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:
    a. cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
    b. not include any sensitive information in the subject or body of any reporting e-mail; and
    c. encrypt sensitive information in attachments to email, media, etc.
4. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.
5. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event

information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation within an hour of discovery.

E. POSITION SENSITIVITY DESIGNATIONS

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract:

[ ] Level 6: Public Trust - High Risk. Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] Level 5: Public Trust - Moderate Risk. Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[X] Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

F. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.

(For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12)

Roster-

1. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx .
2. If the Contractor is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.
3. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

4. The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.
5. All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract. Contractors may begin work after the fingerprint check has been completed.
6. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
7. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).
8. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
9. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.
10. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

G. CONTRACT INITIATION AND EXPIRATION

1. **General Security Requirements-** The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Guide (2012).
   HHS EA requirements may be located here: https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-policy-for-enterprise-architecture.html
   System Documentation- Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, Security Considerations in the System Development Life Cycle, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.
2. **Sanitization of Government Files and Information-** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are

appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

3. **Notification-** The Contractor (and/or any subcontractor) shall notify the CO and/or COR and system ISSO within ***fifteen days*** before an employee stops working under this contract.
4. **Contractor Responsibilities Upon Physical Completion of the Contract-** The contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or NIH policies.
5. The Contractor (and/or any subcontractor) shall perform and document the actions identified in the NIH Contractor Employee Separation Checklist https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf when an employee terminates work under this contract within 2 days of the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.

H. RECORDS MANAGEMENT AND RETENTION

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS/NIH policies and shall not dispose of any records unless authorized by HHS/NIH.

In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS/NIH policies.

ARTICLE H.39.2. PRIVACY ACT

It has been determined that this contract is subject to the Privacy Act of 1974, because this contract provides for the design, development, or operation of a system of records on individuals.

The System of Records Notice (SORN) that is applicable to this contract is located in Attachment 15, Privacy Act System of Records.

The design, development, or operation work the Contractor is to perform is located in Attachment 4, Statement of Work.

The Contractor and any Subcontractor must follow disposition to be made of the Privacy Act records upon completion of contract performance shall be in accordance with Section C of the contract, and by direction of the Contracting Officer/Contracting Officer's representative.

ARTICLE H.39.3. GOVERNMENT INFORMATION PROCESSED ON GOCO OR COCO SYSTEMS

(The Contractor is required to use FedRAMP compliant tools. If the Contractor is unable, the FFRDC CO, FFRDC IT COR and NCI CIO (or other IC CIO as appropriate) must make a determination to accept the risk of using non-FedRAMP compliant tools. This determination must be provided to the Contractor before funds are expended on these tools. If any part of this article cannot be met, the contractor shall

receive approval for an exception from the FFRDC CO, FFRDC IT COR and NCI CIO (or other IC CIO as appropriate) prior to taking any action.)

SECURITY REQUIREMENTS FOR GOVERNMENT-OWNED/CONTRACTOR-OPERATED (GOCO) AND CONTRACTOR-OWNED/CONTRACTOR-OPERATED (COCO) RESOURCES

A. **Federal Policies-** The Contractor (and/or any subcontractor) shall comply with applicable federal laws that include, but are not limited to, the HHS Information Security and Privacy Policy (IS2P), Federal Information Security Modernization Act (FISMA) of 2014, (44 U.S.C. 101); National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, Security and Privacy Controls for Federal Information Systems and Organizations; Office of Management and Budget (OMB) Circular A-130, Managing Information as a Strategic Resource; and other applicable federal laws, regulations, NIST guidance, and Departmental policies.

B. **Security Assessment and Authorization (SA&A)-** A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s). The Contractor shall conduct the SA&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).

   For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such.

   NIH acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

   1. **SA&A Package Deliverables -** The Contractor (and/or any subcontractor) shall provide an SA&A package in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The following SA&A deliverables are required to complete the SA&A package.
      - **System Security Plan (SSP) -** due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The SSP shall comply with the NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems, the Federal Information Processing Standard (FIPS) 200, Recommended Security Controls for Federal Information Systems, and NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline requirements, and other applicable NIST guidance as well as HHS and NIH policies and other guidance. The SSP shall be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP shall provide an overview of the system environment and security requirements to protect the information system as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP at least annually thereafter.
      - **Security Assessment Plan/Report (SAP/SAR) -** due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The security assessment shall be conducted by

the assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and NIH policies. The assessor will document the assessment results in the SAR.

The NIH should determine which security control baseline applies and then make a determination on the appropriateness/necessity of obtaining an independent assessment. Assessments of controls can be performed by contractor, government, or third parties, with third party verification considered the strongest. If independent assessment is required, include statement below.

Thereafter, the Contractor, in coordination with the NIH shall conduct/assist in the assessment of the security controls and update the SAR at least annually.

- **Independent Assessment -** due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The Contractor (and/or subcontractor) shall have an independent third-party validate the security and privacy controls in place for the system(s). The independent third party shall review and analyze the Security Authorization package, and report on technical, operational, and management level deficiencies as outlined in NIST SP 800-53. The Contractor shall address all "high" deficiencies before submitting the package to the Government for acceptance. All remaining deficiencies must be documented in a system Plan of Actions and Milestones (POA&M).
- **POA&M -** due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The POA&M shall be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies. All high-risk weaknesses must be mitigated within 30 days and all medium weaknesses must be mitigated within 60 days from the date the weaknesses are formally identified and documented. The NIH will determine the risk rating of vulnerabilities.

  Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as documented in the SAR, shall be documented and tracked by the Contractor for mitigation in the POA&M document. Depending on the severity of the risks, NIH may require designated POAM weaknesses to be remediated before an ATO is issued. Thereafter, the POA&M shall be updated at least quarterly.
- **Contingency Plan and Contingency Plan Test -** due in accordance with NIH Enterprise Life Cycle (EPLC) requirements prior to the ATO. The Contingency Plan must be developed in accordance with NIST SP 800-34, Contingency Planning Guide for Federal Information Systems, and be consistent with HHS and NIH policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, shall test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned and any action items that need to be addressed. Thereafter, the Contractor shall update and test the Contingency Plan at least annually.
- **E-Authentication Questionnaire -** The contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04 and NIST SP 800-63, Rev. 2, *Electronic Authentication Guidelines.*

Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

2. **Information Security Continuous Monitoring-** Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)-owned/operated systems that input, store, process, output, and/or transmit government information, shall meet or exceed the information security continuous monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800-137, *Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations*, and HHS IS2P. The following are the minimum requirements for ISCM:
   - **Annual Assessment/Pen Test -** Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party. In addition, review all relevant SA&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer's Representative.
   - **Asset Management -** Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS-owned information/data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.
   - **Configuration Management -** Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.
   - **Vulnerability Management -** Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-

compliant automated tools and report to the agency at least within 30 days of the contract award.

- **Patching and Vulnerability Remediation -** Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.
- **Secure Coding -** Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- **Boundary Protection -** The contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).

C. Government Access for Security Assessment. In addition to the Inspection Clause in the contract, the Contractor (and/or any subcontractor) shall afford the Government access to the Contractor's facilities, installations, operations, documentation, information systems, and personnel used in performance of this contract to the extent required to carry out a program of security assessment (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the confidentiality, integrity, and availability of federal data or to the protection of information systems operated on behalf of HHS, including but are not limited to:

1. At any tier handling or accessing information, consent to and allow the Government, or an independent third party working at the Government's direction, without notice at any time during a weekday during regular business hours contractor local time, to access contractor and subcontractor installations, facilities, infrastructure, data centers, equipment (including but not limited to all servers, computing devices, and portable media), operations, documentation (whether in electronic, paper, or other forms), databases, and personnel which are used in performance of the contract.

   The Government includes but is not limited to the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include but not be limited to such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.
2. At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the

Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.

3. Segregate Government protected information and metadata on the handling of Government protected information from other information. Commingling of information is prohibited. Inspectors, auditors, and investigators will not be precluded from having access to the sought information if sought information is commingled with other information.
4. Cooperate with inspections, audits, investigations, and reviews.

D. **End of Life Compliance-** The Contractor (and/or any subcontractor) must use Commercial off the Shelf (COTS) software or other software that is supported by the manufacturer. In addition, the COTS/other software need to be within one major version of the current version; deviation from this requirement will only be allowed via the HHS waiver process (approved by HHS CISO). The contractor shall retire and/or upgrade all software/systems that have reached end-of-life in accordance with HHS End-of-Life Operating Systems, Software, and Applications Policy.

E. **Desktops, Laptops, and Other Computing Devices Required for Use by the Contractor-** The Contractor (and/or any subcontractor) shall ensure that all IT equipment (e.g., laptops, desktops, servers, routers, mobile devices, peripheral devices, etc.) used to process information on behalf of HHS are deployed and operated in accordance with approved security configurations and meet the following minimum requirements:

1. Encrypt equipment and sensitive information stored and/or processed by such equipment in accordance with HHS and FIPS 140-2 encryption standards.
2. Configure laptops and desktops in accordance with the latest applicable United States Government Configuration Baseline (USGCB), and HHS Minimum Security Configuration Standards;
3. Maintain the latest operating system patch release and anti-virus software definitions within 15 days.
4. Validate the configuration settings after hardware and software installation, operation, maintenance, update, and patching and ensure changes in hardware and software do not alter the approved configuration settings; and
5. Automate configuration settings and configuration management in accordance with HHS security policies, including but not limited to:
   - Configuring its systems to allow for periodic HHS vulnerability and security configuration assessment scanning; and
   - Using Security Content Automation Protocol (SCAP)-validated tools with USGCB Scanner capabilities to scan its systems at least on a monthly basis and report the results of these scans to the CO and/or the Information Systems and Technology COR, Project Officer, and any other applicable designated POC.

ARTICLE H.39.4. CLOUD SERVICES

(This article is applicable to the Contractor if they are acting as a cloud service provider. It is also applicable as flow down language to subcontracts with cloud service providers. The Contractor is required to use FedRAMP compliant tools. If the Contractor is unable, the FFRDC CO, FFRDC IT COR and NCI CIO (or other IC CIO as appropriate) must make a determination to accept the risk of using non-FedRAMP compliant tools. This determination must be provided to the Contractor before funds are

expended on these tools. If any part of this article cannot be met, the contractor shall receive approval for an exception from the FFRDC CO, FFRDC IT COR and NCI CIO (or other IC CIO as appropriate) prior to taking any action.)

A. HHS FedRAMP Privacy and Security Requirements

The Contractor (and/or any subcontractor) shall be responsible for the following privacy and security requirements:

1. **FedRAMP Compliant ATO.** Comply with FedRAMP Security Assessment and Authorization (SA&A) requirements and ensure the information system/service under this contract has a valid FedRAMP compliant (approved) authority to operate (ATO) in accordance with Federal Information Processing Standard (FIPS) Publication 199 defined security categorization. If a FedRAMP compliant ATO has not been granted, the Contractor shall submit a plan to obtain a FedRAMP compliant ATO by 30 days of the contract award.
2. A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.
    a. **Data Jurisdiction-** The contractor shall store all information within the security authorization boundary, data at rest or data backup, within the continental United States (CONUS) if so required as stated in section C.
    b. **Service Level Agreements-** The Contractor shall understand the terms of the service agreements that define the legal relationships between cloud customers and cloud providers and work with NIH to develop and maintain an SLA.
    c. **Interconnection Agreements/Memorandum of Agreements-** The Contractor shall establish and maintain Interconnection Agreements and or Memorandum of Agreements/Understanding in accordance with HHS/NIH policies.

B. Protection of Information in a Cloud Environment

1. If contractor (and/or any subcontractor) personnel must remove any information from the primary work area, they shall protect it to the same extent they would the proprietary data and/or company trade secrets and in accordance with HHS/NIH policies.
2. HHS will retain unrestricted rights to federal data handled under this contract. Specifically, HHS retains ownership of any user created/loaded data and applications collected, maintained, used, or operated on behalf of HHS and hosted on contractor's infrastructure, as well as maintains the right to request full copies of these at any time. If requested, data must be available to HHS within one (1) business day from request date or within the timeframe specified otherwise. In addition, the data shall be provided at no additional cost to HHS.
3. The Contractor (and/or any subcontractor) shall ensure that the facilities that house the network infrastructure are physically and logically secure in accordance with FedRAMP requirements and HHS policies.
4. The contractor shall support a system of records in accordance with NARA-approved records schedule(s) and protection requirements for federal agencies to manage their electronic records in accordance with 36 CFR § 1236.20 & 1236.22 (ref. a), including but not limited to the following:
    a. Maintenance of links between records and metadata, and

b. Categorization of records to manage retention and disposal, either through transfer of permanent records to NARA or deletion of temporary records in accordance with NARA-approved retention schedules.

5. The disposition of all HHS data shall be at the written direction of HHS/NIH. This may include documents returned to HHS control; destroyed; or held as specified until otherwise directed. Items returned to the Government shall be hand carried or sent by certified mail to the COR.
6. If the system involves the design, development, or operation of a system of records on individuals, the Contractor shall comply with the Privacy Act requirements.

C. Security Assessment and Authorization (SA&A) Process

1. The Contractor (and/or any subcontractor) shall comply with HHS and FedRAMP requirements as mandated by federal laws, regulations, and HHS policies, including making available any documentation, physical access, and logical access needed to support the SA&A requirement. The level of effort for the SA&A is based on the system's FIPS 199 security categorization and HHS/NIH security policies.
    a. In addition to the FedRAMP compliant ATO, the contractor shall complete and maintain an agency SA&A package to obtain agency ATO prior to system deployment/service implementation. The agency ATO must be approved by the NIH authorizing official (AO) prior to implementation of system and/or service being acquired.
    b. CSP systems categorized as Federal Information Processing Standards (FIPS) 199 high must leverage a FedRAMP accredited third-party assessment organization (3PAO); moderate impact CSP systems must make a best effort to use a FedRAMP accredited 3PAO. CSP systems categorized as FIPS 199 low impact may leverage a non-accredited, independent assessor.
    c. For all acquired cloud services, the SA&A package must contain the following documentation: SSP, SAR, POA&M, Authorization Letter, CP and CPT report, E-Authorization (if applicable), PTA/PIA (if applicable), Interconnection/Data Use Agreements (if applicable), Authorization Letter, Configuration Management Plan (if applicable), Configuration Baseline, Following the initial ATO, the Contractor must review and maintain the ATO in accordance with HHS/NIH policies.
2. HHS reserves the right to perform penetration testing (pen testing) on all systems operated on behalf of agency. If HHS exercises this right, the Contractor (and/or any subcontractor) shall allow HHS employees (and/or designated third parties) to conduct Security Assessment activities to include control reviews in accordance with HHS requirements. Review activities include, but are not limited to, scanning operating systems, web applications, wireless scanning; network device scanning to include routers, switches, and firewall, and IDS/IPS; databases and other applicable systems, including general support structure, that support the processing, transportation, storage, or security of Government information for vulnerabilities.
3. The Contractor must identify any gaps between required FedRAMP Security Control Baseline/Continuous Monitoring controls and the contractor's implementation status as documented in the Security Assessment Report and related Continuous Monitoring artifacts. In addition, all gaps shall be documented and tracked by the contractor for mitigation in a Plan of Action and Milestones (POA&M) document. Depending on the severity of the risks, HHS may require remediation at the contractor's expense, before HHS issues an ATO.

4. The Contractor (and/or any subcontractor) shall mitigate security risks for which they are responsible, including those identified during SA&A and continuous monitoring activities. All vulnerabilities and other risk findings shall be remediated by the prescribed timelines from discovery: (1) critical vulnerabilities no later than thirty (30) days and (2) high, medium and low vulnerabilities no later than sixty (60) days. In the event a vulnerability or other risk finding cannot be mitigated within the prescribed timelines above, they shall be added to the designated POA&M and mitigated within the newly designated timelines 30 days. HHS will determine the risk rating of vulnerabilities using FedRAMP baselines.
5. Revocation of a Cloud Service. HHS/NIH staff division have the right to take action in response to the CSP's lack of compliance and/or increased level of risk. In the event the CSP fails to meet HHS and FedRAMP security and privacy requirements and/or there is an incident involving sensitive information, HHS and/or NIH may suspend or revoke an existing agency ATO (either in part or in whole) and/or cease operations. If an ATO is suspended or revoked in accordance with this provision, the CO and/or COR may direct the CSP to take additional security measures to secure sensitive information. These measures may include restricting access to sensitive information on the Contractor information system under this contract. Restricting access may include disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls.

D. Reporting and Continuous Monitoring

1. Following the initial ATOs, the Contractor (and/or any subcontractor) must perform the minimum ongoing continuous monitoring activities specified below, submit required deliverables by the specified due dates, and meet with the system/service owner and other relevant stakeholders to discuss the ongoing continuous monitoring activities, findings, and other relevant matters. The CSP will work with the agency to schedule ongoing continuous monitoring activities.

   Information Security Continuous Monitoring- Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)-owned/operated systems that input, store, process, output, and/or transmit government information, shall meet or exceed the information security continuous monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800-137, Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations, and HHS IS2P. The following are the minimum requirements for ISCM:

   - **Annual Assessment/Pen Test -** Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party. In addition, review all relevant SA&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer's Representative.
   - **Asset Management -** Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS-owned information/data. It is anticipated

that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.

- **Configuration Management -** Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.
- **Vulnerability Management -** Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-compliant automated tools and report to the agency at least within 30 days of the contract award.
- **Patching and Vulnerability Remediation -** Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.
- **Secure Coding -** Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- **Boundary Protection -** The contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).
- A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.

2. At a minimum, the Contractor must provide the following artifacts/deliverables on a monthly basis as directed by the Contracting Officer/Contracting Officer's Representative.
    a. Operating system, database, Web application, and network vulnerability scan results;
    b. Updated POA&Ms;
    c. Any updated authorization package documentation as required by the annual attestation/assessment/review or as requested by the NIH System Owner or AO; and

d. Any configuration changes to the system and/or system components or CSP's cloud environment, that may impact HHS/NIH's security posture. Changes to the configuration of the system, its components, or environment that may impact the security posture of the system under this contract must be approved by the agency.

E. Configuration Baseline

1. The contractor shall certify that applications are fully functional and operate correctly as intended on systems using the US Government Configuration Baseline (USGCB), DISA Security Technical Implementation Guides (STIGs), Center for Information Security (CIS) Security Benchmarks or any other HHS-identified configuration baseline. The standard installation, operation, maintenance, updates, and/or patching of software shall not alter the configuration settings from the approved HHS/NIH.

- The Contractor shall configure its computers that contain HHS data with the latest applicable United States Government Configuration Baseline (USGCB) and/or other approved HHS IT Security Configurations. (See: https://usgcb.nist.gov/). Note: Approved security configurations include, but are not limited to, those published by the Department, the NIH , and the National Institute of Standards and Technology (NIST) . NIH may have security configurations that are more stringent than the minimum baseline set by the Department or NIST. When incorporating such security configuration requirements in solicitations and contracts, the NIH CISO and/or Information System Security Officer (ISSO) shall be consulted to determine the appropriate configuration reference for a particular system or services acquisition.)
- The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS and must adhere to all NIH configuration standards and policies (See: https://wiki.ocio.nih.gov/wiki/index.php/Configuration_Management_Guidance
- The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with USGCB Scanner capability to ensure its products operate correctly with USGCB configurations and do not alter USCGB settings - (See: http://scap.nist.gov/validation). The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest USGCB major version and subsequent major versions.
- The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
- The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (See: http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of

servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.

- The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

2. The contractor shall use Security Content Automation Protocol (SCAP) validated tools with configuration baseline scanner capability to certify their products operate correctly with HHS and NIST defined configurations and do not alter these settings.

F. Incident Reporting

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within 24 hours, whether the response is positive or negative.

FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII" .

In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) shall:

1. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
2. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals within ***5 business days*** of the incident.
3. Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) IRT@nih.gov **,** COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

a. Cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
b. Not include any sensitive information in the subject or body of any reporting e-mail; and
c. Encrypt sensitive information in attachments to email, media, etc.

4. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.
5. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation.
6. The Contractor (and/or any subcontractor) shall provide an Incident and Breach Response Plan (IRP) in accordance with HHS/NIH, OMB, and US-CERT requirements and obtain approval from the NIH. In addition, the Contractor must follow the incident response and US-CERT reporting guidance contained in the FedRAMP Incident Communications.
7. The Contractor (and/or any subcontractor) must implement a program of inspection to safeguard against threats and hazards to the security, confidentiality, integrity, and availability of federal data, afford HHS access to its facilities, installations, technical capabilities, operations, documentation, records, and databases within 72 hours of notification. The program of inspection shall include, but is not limited to:
    a. Conduct authenticated and unauthenticated operating system/network/database/Web application vulnerability scans. Automated scans can be performed by HHS/NIH personnel, or agents acting on behalf of HHS/NIH, using agency-operated equipment and/or specified tools. The Contractor may choose to run its own automated scans or audits, provided the scanning tools and configuration settings are compliant with NIST Security Content Automation Protocol (SCAP) standards and have been approved by the agency. The agency may request the Contractor's scanning results and, at the agency discretion, accept those in lieu of agency performed vulnerability scans.
    b. In the event an incident involving sensitive information occurs, cooperate on all required activities determined by the agency to ensure an effective incident or breach response and provide all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. In addition, the Contractor must follow the agency reporting procedures and document the steps it takes to contain and eradicate the incident, recover from the incident, and provide a post-incident report that includes at a minimum the following:
        - Company and point of contact name;
        - Contract information;
        - Impact classifications/threat vector;
        - Type of information compromised;
        - A summary of lessons learned; and
        - Explanation of the mitigation steps of exploited vulnerabilities to prevent similar incidents in the future.

G. Media Transport
    1. The Contractor and its employees shall be accountable and document all activities associated with the transport of government information, devices, and media transported outside controlled areas and/or facilities. These include information stored on digital and non-digital media (e.g., CD-ROM, tapes, etc.), mobile/portable devices (e.g., USB flash drives, external hard drives, and SD cards).
    2. All information, devices and media must be encrypted with HHS-approved encryption mechanisms to protect the confidentiality, integrity, and availability of all government information transported outside of controlled facilities.

H. Boundary Protection: Trusted Internet Connections (TIC)
    1. The contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities using cloud services is inspected by Trusted Internet Connection (TIC) processes.
    2. The contractor shall route all external connections through a TIC.
    3. **Non-Repudiation-** The contractor shall provide a system that implements FIPS 140-2 validated encryption that provides for origin authentication, data integrity, and signer non-repudiation.

ARTICLE H.39.5. OTHER IT PROCUREMENTS

ARTICLE H.39.5.1. HARDWARE PROCUREMENTS

(The Contractor is required to use FedRAMP compliant tools. If the Contractor is unable, the FFRDC CO, FFRDC IT COR and NCI CIO (or other IC CIO as appropriate) must make a determination to accept the risk of using non-FedRAMP compliant tools. This determination must be provided to the Contractor before funds are expended on these tools. If any part of this article cannot be met, the contractor shall receive approval for an exception from the FFRDC CO, FFRDC IT COR and NCI CIO (or other IC CIO as appropriate) prior to taking any action.)

A. **Card Readers-** The Contractor (and/or any subcontractor) shall include Federal Information Processing Standard (FIPS) 201-compliant smart card readers (referred to as LACS Transparent Readers) with the purchase of servers, printers, desktops, and laptops.
B. **Mobile Devices-** The contractor shall follow NIST 800-124, Rev. 1, Guidelines for Managing the Security of Mobile Devices in the Enterprise when using mobile devices that process or store HHS data.

ARTICLE H.39.5.2. NON-COMMERCIAL AND OPEN SOURCE COMPUTER SOFTWARE

(If any part of this article cannot be met, the contractor shall receive approval for an exception from the FFRDC CO, FFRDC IT COR and NCI CIO (or other IC CIO as appropriate) prior to taking any action.)
The Contractor (and/or any subcontractor) shall follow secure coding best practice requirements, as directed by the United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP) that will limit system software vulnerability exploits.

ARTICLE H.39.5.3. INFORMATION TECHNOLOGY APPLICATION DESIGN, DEVELOPMENT, OR SUPPORT

(If any part of this article cannot be met, the contractor shall receive approval for an exception from the FFRDC CO, FFRDC IT COR and NCI CIO (or other IC CIO as appropriate) prior to taking any action.)

A. The Contractor (and/or any subcontractor) shall ensure IT applications designed and developed for end users (including mobile applications and software licenses) run in the standard user context without requiring elevated administrative privileges.
B. The Contractor (and/or any subcontractor) shall follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
C. The Contractor (and/or any subcontractor) shall ensure that computer software developed on behalf of HHS or tailored from an open-source product, is fully functional and operates correctly on systems configured in accordance with government policy and federal configuration standards. The contractor shall test applicable products and versions with all relevant and current updates and patches updated prior to installing in the HHS environment. No sensitive data shall be used during software testing.
D. The Contractor (and/or any subcontractor) shall protect information that is deemed sensitive from unauthorized disclosure to persons, organizations or subcontractors who do not have a need to know the information. Information which, either alone or when compared with other reasonably-available information, is deemed sensitive or proprietary by HHS shall be protected as instructed in accordance with the magnitude of the loss or harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the data. This language also applies to all subcontractors that are performing under this contract.

ARTICLE H.39.5.4. PHYSICAL ACCESS TO GOVERNMENT CONTROLLED FACILITIES

Refer to section H.39.1.- INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY.

ARTICLE H.40. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-74 (December 2015)

A. Pursuant to Section 508 of the Rehabilitation Act of 1973(29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards'' set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board'') in 36 CFR part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508 . The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards .
B. The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

C. The Section 508 accessibility standards applicable to this contract are: (Contract staff must list applicable standards)

D. In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Web site: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

E. If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS
Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508 . If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

ARTICLE H.41. COMMUNICATIONS MATERIALS AND SERVICES

To build and maintain public trust; promote credibility and consistency; minimize consistency and frustration; and contribute to efforts aimed at leveraging reduced resources and eliminating waste in Government, the Contractor shall ensure that all materials generated and/or services provided under this contract, comply with all applicable NIH policy and procedures published by the NIH Office of Management Assessment in conjunction with the NIH Office of Communications and Public Liaison as set forth below.

This acquisition requires the contractor to:

[X] Prepare, review, and/or distribute NIH Publications and Audiovisuals.

NIH Policy Manual Chapter 1183, "NIH Publications & Audiovisuals: Preparation, Review, Approval & Distribution," is applicable to this contract.
http://oma1.od.nih.gov/manualchapters/management/1183/ .

[X] Use the NIH name and logo.

NIH Policy Manual Chapter 1186, "Use of NIH Names and Logos," is applicable to this contract.
http://oma1.od.nih.gov/manualchapters/management/1186/ .

[X] Create and/or Manage a Public Website which includes NIH hosted social media site(s), Web application(s) and mobile Web Site(s).

NIH Policy Manual Chapter 2804, "Public-Facing Web Management," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/2804/ .

[X] Create and/or Manage an NIH Website that maintains and disseminates personal information.

NIH Policy Manual Chapter 2805, "NIH Web Privacy Policy," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/2805/ .

[X] Create and/or Manage an NIH hosted and/or funded social media site(s), Web application(s) and mobile Web site(s).

NIH Policy Manual Chapter 2809, "NIH Social and New Media Policy," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/2809/ .

Additional Standards applicable to this contract are identified in the FFRDC Statement of Work and at the Task Order Level. If it is determined by the Government that products, services, and deliverables provided by the Contractor do not conform to standards described in these directives, remediation to an acceptable level of conformance shall be the responsibility of the Contractor at its own expense.

ARTICLE H.42. STORAGE FACILITY REQUIREMENTS AND CERTIFICATION

The Contractor shall ensure that all materials generated under this contract for which commercial records storage is required, shall be stored in a facility that meets National Archives and Records Administration (NARA) requirements for safe, secure and certified storage as required by 36 CFR 1228, subpart K.

The Contractor shall provide the Contracting Officer with the name(s) and location(s) of the commercial records storage facility used to store materials under this contract. In addition, the Contractor shall provide a copy of the "Facility Standards for Records Storage Facilities Inspection Checklist," self-certifying that the facility being used to store federal records meets established NARA standards. NARA Standards are available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=b5a00a361423743ff1a062faafcfdd89&rgn=div5&view=text&node=36:3.0.10.2.23&idno=36

Sixty (60) days prior to contract end date, the Contractor shall submit to the FFRDC-Technical and Scientific Support (COR) and Contracting Officer, an inventory of all materials stored. The disposition of these materials shall be determined no later than the expiration date of the contract.

Additional information about Records Storage Facility Standards can be found at: http://www.archives.gov/records-mgmt/storage-standards-toolkit/

ARTICLE H.43. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the Contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each Contractor employee's

computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

ARTICLE H.44. CONTRACTOR'S USE OF LIBRARY RESOURCES AT NIH

The Contractor is authorized to use library resources at NIH in the same manner as NIH staff. The Contractor's approved use of these resources is limited to performing the requirements of this contract. The Contractor shall not use library resources at NIH in a manner that exceeds the Fair Use limitations codified in 17 U.S.C. sec. 107 of the Copyright Act. Contractors shall not share access to library resources at NIH with, perform searches for, or provide results to, non-NIH users, i.e. collaborators at other universities or research centers.

ARTICLE H.45. CONFIDENTIALITY OF INFORMATION

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

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

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

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

E. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

F. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

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

The following information is covered by this article:

All information under this contract is considered confidential information.

ARTICLE H.46. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: : http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45
As required by 45 CFR Part 94, the Institution shall, at a minimum:

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

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

Significant financial interests do not include the following:

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

B. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

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

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

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

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

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

H. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where

applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

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

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

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

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

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

ARTICLE H.47. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

A. "This project has been funded in whole or in part with Federal funds from the [specify Institute/Center], National Institutes of Health, Department of Health and Human Services, under Contract No. 75N91019D00024."

B. For Manuscripts (Use of NCI Funds):

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, under Contract No. HHSN261201800001I. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government."

For Abstracts: (due to space limitations): Funded by NCI Contract No. 75N910D00024

For Manuscripts (Use of NIH funds): "This research was supported [in part] by the National Institutes of Health"

C. Authors of manuscripts/abstracts have the option of using any or all of the following affiliations:

Option 1) Contractor laboratory name
Option 2) Contractor directorate name

The selected option(s) shall be inserted into the following statement:
Authors Name, (Option 1, 2), Frederick National Laboratory for Cancer Research.

D. The following additional statement is to be included in manuscripts when animal studies have been performed:

"NCI-Frederick is accredited by AAALAC International and follows the Public Health Service Policy for the Care and Use of Laboratory Animals. Animal care was provided in accordance with the procedures outlined in the "Guide for Care and Use of Laboratory Animals (National Research Council; 1996; National Academy Press; Washington, D.C.)."

E. If Government employee(s) are identified on a publication as a primary author(s) of scientific or technical article(s), then the Contractor shall obtain the concurrence to copyright through the participating Government employee(s). In turn, the Government employee shall be responsible for assuring that appropriate approvals are obtained. If the author(s) are Contractor employees, then the Contractor shall be guided by the contract data rights clauses.

F. Advanced Copies of Press Releases

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The Contractor shall not publish a press release related to this contract without receiving prior concurrence from the FFRDC-Technical and

Scientific Support COR. The Contractor shall submit an advance copy of the press release to the Contracting Officer and FFRDC-Technical and Scientific Support COR. Upon acknowledgment of receipt, the Contracting Officer will have five (5) working days to respond with concurrence or comments. In the event that the Contracting Officer does not communicate concurrence or comments to the Contractor within five (5) working days following acknowledgement of receipt of the press release advance copy, concurrence may be presumed.

ARTICLE H.48. REVIEW OF MANUSCRIPTS

In order to balance the oversight responsibility of the National Cancer Institute (NCI) with the authorization provided to the Contractor by the Rights in Data clause, 52.227-14 of this contract, the NCI does not require contractors to seek the Institute's approval of manuscripts and abstracts; however, Government review of manuscripts and abstracts is required. This review process applies to Contractor authored or co-authored manuscripts and abstracts. Government authored or co-authored manuscripts and abstracts do not follow this review process. The Contractor shall provide advance notice of intent to submit a manuscript to a peer reviewed journal for publication at least 10 business days prior to submission to the publisher to the appropriate Division, Office, or Center (DOC)Point of Contact. The advance notice should briefly describe the plans for publication of the manuscript and include a copy of the manuscript. Manuscripts are defined as: a scientific or technical report or abstract to be submitted to a peer-reviewed journal or conference for publication. The Contractor shall provide advance notice of intent to submit an abstract to a conference for publication at least2 business days prior to submission to the publisher to the appropriate Division, Office, or Center (DOC) Point of Contact. The advance notice should briefly describe the plans for publication of the abstract and include a copy of the abstract. An abstract is defined as any document that summarizes a professional publication, i.e. research article, thesis, review, conference proceeding or any in-depth analysis of a particular subject or discipline. Any comments from the DOC Point of Contact will be provided in writing within the 10 business day review period for manuscripts and within the 2 business day review period for abstracts. In the event that no comments are received in the specified timeframes allotted above, it will result in "review with no comments" and the Contractor may proceed with submittal. Comments expressed by the DOC Point of Contact about the manuscript shall not be a cause for action under the Disputes clause of the contract by either NCI or the Contractor.

ARTICLE H.49. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS

P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.50. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.
Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

A. Sharing of Model Organisms for Biomedical Research

The plan for sharing model organisms will be submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

B. Transfer of Human Materials

All human materials transferred to the contractor under this contract for the purposes of research shall be accomplished in accordance with the Policy entitled, "Policy for the Transfer of Materials from NIH Intramural Laboratories," located at:
https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/500-A-Policy.pdf

The contractor shall coordinate with the **NCI Technology Transfer Center** (see http://ttc.nci.nih.gov) to determine the specific terms and conditions for the human materials to be transferred. Generally, the Government and Contractor will enter into Material Transfer Agreement which stipulates the specific terms and conditions relating to the materials being transferred.

ARTICLE H.51. SHARING RESEARCH DATA

The data sharing plan submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.52. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The work being conducted under this contract may involve the possession, use, or transfer of a select agent or toxin. The contractor shall not conduct work involving a select agent or toxin under this contract until it and any associated subcontractor(s) comply with the following:

Domestic institutions. For prime or subcontract awards to domestic institutions that possess, use, and/or transfer a select agent or toxin under this contract, the institution must comply with the provisions of Federal Select Agent Program (http://www.selectagents.gov/index.html) 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 as required, before using NIH funds for work involving a select agent or toxin. No NIH funds can be used for research involving a **select agent or toxin** at a domestic institution without a valid registration certificate.

Foreign institutions. For prime or subcontract awards to foreign institutions that possess, use, and/or transfer a select agent or toxin, before using NIH funds for any work directly involving a select agent or toxin, the foreign institution must provide information satisfactory to NIAID that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 are in place and will be administered on behalf of all select agent or toxin work supported by these funds.

The process for making this determination includes a site visit to the foreign laboratory facility by an NIAID representative. During this visit, the foreign institution must provide the following information:

- Concise summaries of safety, security, and training plans.
- Names of individuals at the foreign institution who will have access to the select agent or toxin and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the select agent or toxin under the contract.
- Copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents.
- Site visits to foreign laboratories are conducted every three years after the initial review.
- No NIH funds can be used for work involving a **select agent or toxin** at a foreign institution without written approval from the contracting officer.

Prior to conducting a restricted experiment with a select agent or toxin under this contract or any associated subcontract, the contractor must discuss the experiment with the contracting officer's representative (COR) and request and obtain written approval from the contracting officer.

Domestic institutions must submit to the contracting officer written approval from the CDC to perform the proposed restricted experiment.

Foreign institutions require review by a NIAID representative. The prime contractor must contact the COR and the NIAID Office of Extramural Research Policy and Operations at DEAPolicyShop@niaid.nih.gov (link sends e-mail) for guidance on the process used by NIAID to review proposed restricted experiments. The NIAID Web site provides an overview of the review process at Review and Approval for Contracts That Include Foreign Institutions. The contracting officer will notify the prime contractor when the process is complete. **No NIH funds can be used for a restricted experiment with a select agent or toxin at either a domestic or foreign institution without written approval from the contracting officer.**

Listings of HHS and USDA select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Federal Select Agent Program (http://www.selectagents.gov/) Web site and Select Agents and Toxins List (http://www.selectagents.gov/SelectAgentsandToxins.html).

For foreign institutions, see https://www.niaid.nih.gov/grants-contracts/select-agents.

ARTICLE H.53. HIGHLY PATHOGENIC AGENTS

The work being conducted under this contract may involve a *Highly Pathogenic Agent (HPA).* The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

A. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)(http://www.cdc.gov/biosafety/publications/index.htm under "Publications);
B. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or
C. The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

ARTICLE H.54. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at:
http://apps.usfa.fema.gov/hotel/ .

ARTICLE H.55. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor 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 Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

ARTICLE H.56. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

ARTICLE H.57. REGISTRATION FEES FOR CONFERENCES, WORKSHOPS AND MEETINGS

A Non-Federal entity co-sponsoring a conference with an Institute/Center (IC) under a contract may charge and collect a registration fee from all participants for the purpose of defraying its portion of the expenses of the conference. Under these circumstances, the Contractor shall document that the registration fees associated with the event are being charged, collected and used solely by the co-sponsor.
Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government's estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted by the Contractor from the total cost of the conference.

In addition, prior to each conference, the Contractor shall provide the following information and documentation to the Contracting Officer's Representative (COR) and Contracting Officer:

A. Co-sponsor's name
B. Conference name, location, dates, times
C. copy of the agenda
D. A completed 'Contractor Pre-Conference Expense Offset Worksheet" (Attachment provided in SECTION J).
E. After the conference is held, the Contractor shall submit a completed "Post-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the COR and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the COR and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the Contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury. If the registration fees collected are in excess of the

uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.
Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the "Post-Conference Expense Offset Worksheet" has been approved by the COR.

ARTICLE H.58. REGISTRATION FEES FOR NIH SPONSORED SCIENTIFIC, EDUCATIONAL, AND RESEARCH-RELATED CONFERENCES

In accordance with the NIH Reform Act of 2006, P.L. 109-482, the NIH may authorize a Contractor procured to assist in the development and implementation of a scientific, educational or research-related conference to collect and retain registration fees from Non-HHS Federal and Non-Federal participants to defray the costs of the contract.

Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government's estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted from the total cost of the conference.

Prior to each conference, the Contractor shall submit a completed "Contractor Pre-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the Contracting Officer's Representative (COR) and Contracting Officer. After the conference is held, the Contractor shall submit a completed "Post-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the COR and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the COR and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury.

If the registration fees collected are in excess of the uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.

Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the "Post-Conference Expense Offset Worksheet" has been approved by the COR.

ARTICLE H.59. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES

Pursuant to the NIH Revitalization Act (P.L. 103-43, Section 206), which adds Section 402(b) to the Public Health Service Act, it is required that NIH, "in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." In addition, Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 require reasonable accommodations to be provided to individuals with disabilities.

It is NIH policy that organizers of scientific meetings should make a concerted effort to achieve appropriate representation of women, racial/ethnic minorities, and persons with disabilities, and other individuals who have been traditionally underrepresented in science, in all NIH sponsored and/or supported scientific meetings.

Therefore, it is the contractor's responsibility to ensure the inclusion of women, minorities, and persons with disabilities in all events when recruiting speakers and/or participants for meetings or conferences funded by this contract.

See the policy announcement for additional details and definitions at:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html

ARTICLE H.60. USE OF FUNDS FOR PROMOTIONAL ITEMS

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

ARTICLE H.61. CONTINUITY OF SERVICES

A. In recognition of the fact that the functions covered under this contract are in support of NCI programs, and require uninterrupted performance; that upon expiration of this contract, the services hereunder may be provided by a successor Contractor and any successor will require phase-in training; that the retention of personnel experienced in the work covered hereunder by any successor is important to the Government; and that a successor's ability to retain such personnel may be significantly enhanced if such personnel can remain without unreasonable loss of earned fringe benefits; the Contractor shall:

    1. Provide, as an allowable cost, the necessary resources to complete those work items commenced during the period of this contract or any renewal thereof, which would not otherwise have been completed within such a period;

2. Provide phase-in, phase-out services for a period not less than thirty (30) days, and up to the period of time set forth in FAR 52.237-3(b), commencing the day after expiration of the contract, to the extent required by the Government, and expeditiously negotiate an equitable adjustment to the estimated cost of the contract for such services, to be provided by continuing the assignment of qualified personnel then currently assigned to the contract.

3. Transfer to any successor Contractor(s) all accrued employment benefits, both vested and non-vested, and, where applicable and as discussed below, the funds accrued for those benefits and any personnel data for those incumbent employees who become employees of the successor Contractor. This transfer shall include, but not necessarily be limited to, all accrued sick leave, vacation, pension benefits, and other employee-related benefits and data as may be required to provide for the uninterrupted accrual and administration of the employees' personnel and fringe benefits program.

4. Vacation Benefits: The Contractor shall transfer funds to the successor Contractor(s) in an amount equal to the dollar value of the accrued vacation liability assumed by the successor Contractor(s).

5. Retirement Programs:
   a. In the event there is a successor Contractor: The successor Contractor shall adopt, as plan sponsor, Retirement Plans A & B (the "Plans") as defined in Article B.4.I. The successor Contractor shall also assume sponsorship of the Plans' respective Trusts and assets. The successor Contractor shall become solely responsible for any and all obligations to participants in the Plans as a result of the transfer in total to the successor Contractor of assets and liabilities of the Plans.

      In regard to Cost Accounting Standards (CAS), Sections 412 and 413, any CAS pre-payment credit shall be returned to the predecessor Contractor by the successor Contractor; and any amount the predecessor Contractor accumulated in accordance with 48 CFR 9904.412-50(a)(2) shall be payable by the predecessor Contractor to the successor Contractor in a timely manner. As described in Section 1116(f)(5) of the Tax Reform Act of 1986, Public Law 99-514, Special Rule for Qualified Offset Arrangements, the employer is the FNLCR.

      The amount of pension liability shall be based on the most recent actuarial calculation completed by the plan actuary. The amount of the assets that shall be transferred by the Contractor to the successor Contractor shall equal the assets in the Plans' respective Trusts. The Government shall approve assets and liabilities as being properly calculated in compliance with applicable Cost Accounting Standards.

      The Government shall include in any successor contract such terms and conditions as are needed to give this Article full force and effect.

b. In the event there is not a successor Plan Sponsor: At the end of this contract, if the contract is not extended or renewed and there is no successor contract or a successor Contractor is not required to assume Sponsorship of the Plans, or upon a "segment closing", a plan "termination" or a plan "curtailment," as these three terms are defined in Cost Accounting Standard 413, this Standard shall determine the requirements for measuring, assigning and, allocating pension costs. The Government and the Contractor acknowledge that as an FFRDC, the Contractor has only one objective which is to operate the FFRDC; therefore, when the contractor is required to measure, assign and allocate an adjustment amount, the government's participation level is expected to be 100%.

B. Furthermore, the Contractor and Government recognize that due to the long-term nature of the FFRDC's research mission, there may be activities, including acquisitions, initiated under the current contract that will extend into the term of a successor contract. Examples of these activities include, but are not limited to i) agreements such a Cooperative Research and Development Agreements (CRADAs), ii) subcontracts for alterations, renovations, and research support services, and iii) cGMP quality biopharmaceutical products manufactured under the current contract that will be used in clinical studies during the term of the successor contract. Accordingly, the following conditions will apply under this contract:

1. The phase-in support services referred to in this Article shall apply to the situations described above and other comparable contract activities that will continue under a successor contract.

2. The successor contractor shall maintain a Medical Products Liability Insurance program that includes the predecessor Contractor as a named insured and provides a comparable level of coverage and protection as that which is in effect under the current contract and meets the conditions negotiated with the Contractor concerning Product Liability Insurance and Licensing.

3. The successor contractor shall assume responsibility for bringing acquisitions initiated by the predecessor Contractor to an orderly conclusion. All subcontracts having anticipated completion dates beyond the expiration date of the Contract shall be novated/transferred to the successor contractor.

C. Within thirty (30) days after contract award by the Government to a successor contractor, the current Contractor shall jointly prepare with said successor a mutually agreeable plan for phase-in, phase-out operations. The plan shall set forth in detail the training program for the successor with a proposed date by which the successor will assume responsibility for work performance. Prior to said date the current Contractor shall retain full responsibility for work performed. Upon request, this plan shall be submitted to the NCI Contracting Officer for approval.

D. This plan shall include all Contractor employee payrolls, health benefits, pension plans, etc.

E. The Contractor shall transfer to any successor Contractor(s) all non-proprietary or privileged internally and externally generated technical, business, financial, administrative, and engineering manuals, user guides, documentation, studies, reports, patent applications, business records,

Standard Procedures (SPs), Standard Operating Procedures (SOPs), produced and paid for under this Contract or acquired by the Contractor from any predecessor Contractor of this FFRDC. This requirement will cover both physical and electronic media. The Contractor also agrees to make all of the above available for review by the Contracting Officer upon request.

ARTICLE H.62. OBSERVANCE OF FORT DETRICK REGULATIONS

Because the NCI Campus at Frederick is located adjacent to Fort Detrick, the Contractor and its employees shall observe the rules and regulations as prescribed by the authorities of that installation. In the event the Contractor deems such rules and regulations to be not applicable or inappropriate, written relief or deviation thereto shall be requested from the Contracting Officer.

ARTICLE H.63. ORGANIZATIONAL CONFLICTS OF INTERESTS

A. Purpose. The purpose of this Article is to ensure that the Contractor) (1) is not biased because of its financial, contractual, organizational, or other interests which relate to the work under this contract, and (2) does not obtain any unfair competitive advantage over other parties by virtue of its performance of this contract.

B. Scope. The restrictions described herein shall apply to performance or participation by the Contractor when it uses any of its affiliates or their successors in interest in the activities covered by this Article as a subcontractor, co-sponsor, joint venture, consultant, or in any similar capacity. For the purpose of this Article, affiliation occurs when a business concern is controlled by or has the power to control another or when a third party has the power to control both.

C. Background. The Contractor is required to conduct its business in a manner befitting its special relationship with the Government, to operate in the public interest with objectivity and independence, to be free from organizational conflicts of interest, and to have full disclosure of its affairs to the Government. FAR 9.502 (c) states: “An organizational conflict of interest may result when factors create an actual or potential conflict of interest on an instant contract, or when the nature of the work to be performed on the instant contract creates an actual or potential conflict of interest on a future acquisition.”

Due to the requirements and unusual (sometimes unique) nature of the work performed under this contract, and the fact that the Contractor is operating an FFRDC in Government owned facilities, the Government must maintain a special, close relationship with the Contractor’s personnel in various important areas (e.g., access to Government and supplier data, including sensitive and proprietary data, employees and facilities, safety, security, cost control, and site conditions). This relationship has the potential to give the Contractor access to information that the Government considers privileged, including proprietary information of third parties and non-public Government deliberations, recommendations, and advice. Examples include, but are not limited to, NIH and NCI program plans, policies, reports, studies, and financial plans that are not publicly available. The Contractor shall not use this privileged information or access to facilities to compete with the private sector for other Government contracts.

D. Restrictions. FAR 35.017-1 (c) (4) states that an FFRDC sponsoring agreement must address the following: “A prohibition against the FFRDC competing with any non-FFRDC concern in response to a Federal agency request for proposal for other than the operation of an FFRDC. This prohibition is not required to be applied to any parent organization or other subsidiary of the parent organization in its non-FFRDC operations. Requests for information, qualifications or capabilities can be answered unless otherwise restricted by the sponsor.” In this instance, the Contractor is a wholly owned subsidiary of its parent (Corporate). As a result, this prohibition does not apply to the parent organization or other subsidiary of the parent organization in its non-FFRDC operations.

1. Use of Contractor's Work Product
    a. The Contractor shall be ineligible to participate in any capacity in Government contracts, subcontracts, or proposals therefore (solicited and unsolicited) which stem directly from the Contractor's performance of work under this contract for a period of one (1) year after the completion of this contract. Furthermore, unless so directed in writing by the Contracting Officer, the Contractor shall not perform any advisory and assistance services work under this contract on any of its products or services or the products or services of another firm if the Contractor is or has been substantially involved in their development or marketing. Nothing in this subparagraph shall preclude the Contractor from competing for follow-on contracts.
    b. If, under this contract, the Contractor prepares a complete or essentially complete statement of work or specifications to be used in competitive acquisitions, the Contractor shall be ineligible to perform or participate in any capacity in any contractual effort which is based on such statement of work or specifications. The Contractor shall not incorporate its products or services in such statement of work or specifications unless so directed in writing by the Contracting Officer, in which case the restriction in this subparagraph shall not apply.
    c. Nothing in this Article shall preclude the Contractor from offering or selling its standard and commercial items to the Government, or from competing for a Cooperative Research and Development Agreement (CRADA).

2. Access to and use of information
    a. If the Contractor, in the performance of this contract, obtains access to information, such as Government plans, policies, reports, studies, financial plans, internal data protected by the Privacy Act of 1974 (5 U.S.C. 552a), or data which has not been released or otherwise made available to the public, the Contractor agrees that without prior written approval of the Contracting Officer it shall not—
    b. use such information for any private purpose unless the information has been released or otherwise made available to the public;
    c. compete for work for the Government based on such information for a period of one (1) year after either the completion of this contract or until such information is released or otherwise made available to the public, whichever is first;
    d. submit an unsolicited proposal to the Government which is based on such

information until one year after such information is released or otherwise made available to the public; and

e. release such information unless such information has previously been released or otherwise made available to the public by the Government.

3. In addition, the Contractor agrees that to the extent it receives or is given access to proprietary data, data protected by the Privacy Act of 1974 (5 U.S.C. 552a), or other confidential or privileged technical, business, or financial information under this contract, it shall treat such information in accordance with any restrictions imposed on such information.

4. The Contractor may use technical data it first produces under this contract for its private purposes consistent with paragraphs (b)(2)(i) (A) and (D) of this clause and the patent, rights in data, and security provisions of this contract.

E. Disclosure after award. The Contractor shall make an immediate and full disclosure in writing to the Contracting Officer of any new organizational conflicts of interest that may arise during performance of this contract or any material changes to those previously identified. Such disclosure may include a description of any action which the Contractor has taken or proposes to take to avoid, neutralize, or mitigate any resulting conflict of interest.

F. Waiver. Requests for waiver under this clause shall be directed in writing to the Contracting Officer and shall include a full description of the requested waiver and the reasons in support thereof. If it is determined to be in the best interests of the Government, the Contracting Officer may grant such a waiver in writing.

ARTICLE H.64. EXCHANGE OF CONFIDENTIAL INFORMATION AND RESEARCH MATERIALS

A. Confidentiality

Pursuant to federal law (18 U.S.C. 1905, 15 U.S.C. 3710(a), 5 U.S.C. 552 (b) (4), 45CFR 46) and NIH policy (Standards of Ethical Conduct for Employees of the Executive Branch, 2635.703), NCI employees are obligated to maintain confidential information in confidence as part of their official duties. Contractor employees are hereby required to maintain confidential information confidential in their official duties to the same extent as NCI employees. Therefore, other sections of this contract notwithstanding, contractor employees will keep information identified as or reasonably known to be confidential, including but not limited to, information belonging to the Government or information provided to the Government under a properly executed agreement (e.g., MTA, CDA, CRADA, MCRADA, CTA, Collaboration Agreement). Such obligations are documented in such transactional agreements substantially similar to those agreements currently found on the NCI Technology Transfer Center website (http://ttc.nci.nih.gov). Furthermore, the contractor will flow down this obligation in its subcontracts and other agreements as appropriate. NCI agreements while not signed by the Contractor will reflect the potential for the Contractor to receive materials or information provided to NIH and that such materials and information will be handled by the Contractor consistent with its obligations herein.

The contractor may independently receive third-party confidential information that was not originally intended to be shared with the NCI or other Government users of the contract as part of the contract management (e.g., pursuant to FAR Clause 52.215-2, Audits and Records-Negotiation). In the course of managing the contract, if the contractor identifies such third-party confidential information as confidential, NCI and other Government users of the contract will keep such third-party confidential information confidential to the best of its ability according to policy and to the extent permitted by law.

No party will be obligated to keep information confidential: (i) that can be demonstrated to have been in the public domain or publicly known at the time of disclosure; or (ii) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to such Party from another source prior to the disclosure; or (iii) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by such Party; or (iv) that can be demonstrated as independently developed or acquired by such Party without reference to or reliance upon such Confidential Information; or (v) that is required to be disclosed by law or court order.

B. Third-party Materials Provided to NIH

Pursuant to federal law (15 U.S.C. 3710(a), 42 U.S.C., 241(a), 282(c), 284 (b)(1)(F)) and NIH policy (PHS Technology Transfer Manual, Chapters 400 & 500), NCI employees are obligated to retain appropriate control over third-party materials provided to NIH as part of their official duties. Such obligations are documented in transactional agreements (e.g., MTA, CRADA, MCRADA, CTA, Collaboration Agreement) substantially similar to those agreements currently found on the NCI Technology Transfer Center website (http://ttc.nci.nih.gov). Contractor employees are hereby required to maintain control over third- party materials provided through NIH from such third parties as part of their official duties to the same extent as NCI employees.

ARTICLE H.65. TELEWORK

In order to promote an active Contractor telework program including ad hoc telework for inclement weather and times of facility shut down, the Contractor shall maintain a telework SOP consistent with the NIH's telework program. The Contractor shall provide written advanced notification to the Contracting Officer and COR responsible for the Contractor directorate into which a Contractor teleworking position shall report when any telework agreement expressly provides for telework for a period three (3) or more full days per week for 2 consecutive months or more per calendar year.

When a Government concern arises, the Government shall provide a written, detailed and objective basis for the concerns for reevaluation and any corrective action by the Contractor. The Contractor shall maintain data related to the telework agreements including the number of telework agreements, employee names, job titles and type of agreement (as defined by Contractor policy). Such data shall be made available to the Contracting Officer upon request.

ARTICLE H.66. NOVATION

Any execution of a novation agreement with a successor in interest to this contract shall be handled in accordance with the policies and procedures prescribed in FAR Subpart 42.12.

ARTICLE H.67. HAZARDOUS MATERIALS

Hazardous materials are managed in accordance with the EHS Program Description Document. In the event it is alleged that Contractor caused environmental releases in or about the place of performance of this contract, or if contract performance gives rise to any similar environmental issue, the following will apply.

A. If the Contractor incurs costs, expenses, damages, or liabilities to third parties (third-party liability), to an extent not otherwise compensated by the contract, the protections offered by the combination of in-place operational safety management procedures (to mitigate the effects of the incident), existing (but limited) insurance programs, and FAR clause 52.228-7 will be relied upon.

B. If the Contractor is required by federal, state, or local government agency or court order to take action, or with NCI approval, takes action in connection with an environmental release, the resulting costs will be allowable and allocable to the contract, and NCI will reimburse the Contractor for these costs, subject to the limits set forth in FAR clause 52.232-22, Limitation of Funds. If such actions result in loss or damage to government property, such costs will be allowable only to the extent that the costs are not the direct result of willful misconduct or lack of good faith on the part of the Contractor's directors, officers, or equivalent-level personnel.

C. If the Contractor, in the course of performing its obligations under the contract, is assessed fines or penalties as a result of acts or omissions by government personnel or third parties (e.g., other NCI contractors), rather than as a result of its own acts or omissions or those of its subcontractors, the resulting costs will be allowable and allocable to the contract per FAR 31.205-15, and NCI will reimburse the Contractor for these costs, subject to the limits set forth in FAR clause 52.232-22, Limitation of Funds.

ARTICLE H.68. PERFORMANCE GUARANTEE AGREEMENT

The Contractor's parent organization shall guarantee performance
of the contract as evidenced by the Performance Guarantee Agreement incorporated in the contract in Section J, Attachment 17. In the event any of the signatories to the Performance Guarantee Agreement enters into proceedings related to bankruptcy, whether voluntary or involuntary, the Contractor agrees to furnish written notification of the bankruptcy to the Contracting Officer.

ARTICLE H.69. RESPONSIBLE CORPORATE OFFICIAL

Notwithstanding the provisionsH.68 , the Government may contact, as necessary, the single

responsible corporate
official identified below, who is at a level above the Contractor and who is accountable for the performance of the Contractor, regarding Contractor performance issues. Should the responsible corporate official change during the period of the contract, the Contractor shall promptly notify the Government of the change in the individual to contact.

Name: Jonathan Scholl
Position: President
Organization: Leidos Corporation, Health Group
Address: 11955 Freedom Drive, Reston, VA 20190

ARTICLE H.70. SEPARATE CORPORATE ENTITY

The Contractor under this Contract shall be a separate corporate entity from its parent company. The separate corporate entity may be a partnership or joint venture. The separate corporate entity must be set up solely to perform this Contract and shall be totally responsible for all Contract activities. The separate corporate entity shall perform no other commercial work or work for other Government agencies except as may be authorized under the terms of this contract. The Contractor shall not utilize or otherwise divert contract employees to other corporate work except as may be authorized under the terms of the contract or as otherwise authorized by the Contracting Officer.

ARTICLE H.71. PRODUCT LIABILITY INSURANCE AND LICENSING (Applicable to cGMP projects)

In order to mitigate risks associated with cGMP activities, the following integrated elements of the Contractor's risk management approach are deemed acceptable to the Government: (1) purchase of commercially available medical products liability insurance in the amount of $50 Million in the aggregate for NIH or non-NIH activities, (2) restrictions on the quantity of cGMP materials produced to that required to conduct clinical trials and associated pre-clinical studies and monitoring during the term of any task order and for a 36 month period after the expiration of an applicable task order, and (3) any Government executed license agreement (or similar transaction) with a third party related to any cGMP products or any intellectual property developed, in whole or in part, by the Contractor related to cGMP products, under any task order, will include the Licensing Agreement Language stated below which requires the licensee (or any sublicensee) to indemnify and hold harmless, the Contractor. This language shall be included by the Government in all agreements, unless there is a compelling reason for non-inclusion such as an imminent public health concern. Under these rare situations, the Contractor will be permitted to take other appropriate risk management measures subject to the approval of the Contracting Officer. The Contractor will be provided with a copy of any licensing agreement that includes the "Licensing Agreement Language". If the licensing agreement substantially alters the liability to the Contractor then, prior to execution of the license agreement, the Contractor will be afforded the opportunity to review any changes in the language.

License Agreement Language: The following wording will be included in any license agreement or similar transaction for all cGMP products manufactured by Contractor or other intellectual property developed by the Contractor and assigned to the Government in accordance with the Contract:

Licensee (or any sublicensee) shall indemnify and hold the Government and its employees, students, fellows, agents, NCI-FFRDC contractor (including its officers, directors, employees, or agents), and any consultants acting on behalf of the Government or the NCI-FFRDC Contractor harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of a) the use by Licensee (including any sublicensee), its directors, employees, or third parties of any Licensed Intellectual Property or b) the design, manufacture, distribution, or use of any Licensed Products or other products or processes developed in connection with or arising out of the Licensed Intellectual Property. Licensee (or any sublicensee) agrees to maintain a liability insurance program consistent with sound business practice.

ARTICLE H.72. TECHNOLOGY TRANSFER

In furtherance of the mission at FNLCR the Contractor may employ various technology transfer instruments and activities as appropriate. These may include but are not limited to: Government Cooperative Research and Development Agreements (CRADAs); Contractor CRADAs; Material Transfer Agreements (MTAs) and Collaboration Agreements (CAs). All Contractor CRADAs and related documents, shall include a notice to third parties that the export of goods and/or Technical Data from the United States may require an export control license from the U.S. Government.

The Contractor retains rights to inventions developed under the Contractor CRADA mechanisms pursuant to this contract and FAR 52.227-11 Patent Rights, Ownership by the Contractor APRIL 2017 (Deviation). Such rights will be assigned by the Contractor to any successor-in-interest upon termination of this contract.

ARTICLE H.73. SPECIAL CONTRACT REQUIREMENTS FME/EHS

THESE SPECIAL REQUIREMENTS ARE APPLICABLE TO FACILITIES'MAINTENANCE AND ENGINEERING (FME) AND ENVIRONMENT, HEALTH AND SAFETY (EHS) ONLY.

A. NCI RIGHTS

1. INSPECTIONS/INVESTIGATIONS
    a. The COR-FME/COR-EHS may, in any reasonable manner, observe and inspect the contractor's safety and accident prevention procedures for all activities and personnel. This specifically includes, but it not limited to, the right to attend all safety meetings.

    b. Upon request, the COR-FME/COR-EHS shall receive copies of any safety inspection reports completed by the contractor or anyone performing work for, on behalf of or under the auspices of the contractor.

c. The COR-FME/EHS may, in any reasonable manner, observe or participate in any accident investigation conducted by the contractor or anyone performing work for, on behalf of or under the auspices of the contractor. The NCI may also, at its sole discretion and in any reasonable manner, undertake its own accident investigation.

2. CORRECTIVE ACTIONS/STOP WORK

a. The COR-FME/COR-EHS shall have the right to direct the contractor to correct unsafe working conditions, including taking corrective action when unsafe working conditions are observed (i.e. lack of good housekeeping practices, use of equipment in obviously poor condition, failure to adhere to statutory OSHA regulations, etc.). When unsafe working conditions are observed involving a subcontractor of Leidos Biomedical Research, Inc., any communication or direction must be in writing from the Government to the *Leidos Biomedical Research, Inc. Manager, Construction and Facilities Services Subcontracts* to request corrective action. In the event conditions pose imminent danger or serious harm, written notice should be provided by the Government to the Subcontracts Department as soon as practicable, after the Government provides direction to a subcontractor.

b. The COR-FME/COR-EHS shall have the right to require the removal, from the work site, any person, property or equipment that, in the NCI's opinion, is deemed unsafe.

c. The COR-FME/COR-EHS shall have the right to instruct the contractor to immediately cease any action and/or stop work (or any action thereof) when any conditions exist that, in the NCI's opinion, constitutes an imminent danger or could result in serious harm.

d. The COR-FME/COR-EHS shall have the right to suspend the work pending the completion of any accident/incident investigation, whether undertaken by contractor, the NCI or others.

e. The contractor is responsible for costs, expenses and other obligations paid or incurred by the Contractor, as a result of the contractor or subcontractor's noncompliance with federal, state, or local safety regulations; or failure to comply with terms and conditions of this contract.

3. NCI'S ACTION/INACTION DOES NOT RELIEVE CONTRACTOR

Nothing the NCI may do, or fail to do, with respect to safety in the performance of the work shall relieve the contractor of its responsibility to comply strictly with this Contract and all standards referenced herein.

B. WORK BY THE GOVERNMENT

The Government reserves the right to undertake performance by Government forces or other Contractors, the same type or similar work as contracted for herein, as the Government deems necessary or desirable, and to do so will not breach or otherwise violate this contract.

1. General. The Government has awarded and will award other contracts for specialized work, which is outside the scope of this contract. These contracts will involve additional work at or near the site of the work under this contract. The contractor shall carefully adapt its schedule and performance of work under this contract to accommodate the work of the Other Government Contractors (OGCs), and shall take coordinating direction from the COR-FME. The OGCs will be placed under similar contracting conditions regarding coordination. The Contractor shall make every reasonable effort to avoid interference with the performance of work by the OGCs, as scheduled by the OGCs or by the Government.

2. Notification of Obstructive conditions. If any part of the Contractor's work is impeded by unscheduled occupation or obstruction of Contractor work areas by OGCs, the Contractor shall promptly report such conditions in writing to the COR-FME.

3. Preparation of and access to OGC Worksites. The Contractor shall be responsible to make ready applicable areas to allow for scheduled activities by each of the OGCs in accordance with the project schedule.

4. Notification of Scheduling Conflicts. If the Contractor becomes aware of potential scheduling conflicts with activities by OGCs, the Contractor shall promptly notify the COR-FME in writing.

5. Compliance with Environment, Health, and Safety Requirements. The OGCs will be placed under contracting conditions to require compliance with federal, state, and local (to include Fort Detrick) regulations, requirements, permits, and licenses. The OGC will be required to comply with any FNLCR Contractor held permits or licenses (e.g., wastewater discharge permits, Nuclear Regulatory Commission licenses). The OGC will be required to coordinate activities with FNLCR's EHS Directorate that have the potential to impact the safety and health of FNLCR and NCI at Frederick employees and visitors. The FNLCR Contractor is not responsible for providing oversight, coordination, or review of OGC safety or environmental plans, procedures, training, and activities, but if non-compliances are observed by FNLCR safety and environment professionals, they will be reported to the COR-EHS. FNLCR EHS safety and environment professionals shall have the right to instruct the contractor to immediately cease any action and/or stop work (or any action thereof) when any conditions exist that, in EHS' opinion, constitutes an imminent danger or could result in serious harm. Such actions will be reported to the COR-EHS immediately (verbal or email).

C. SUPPORT OF NIH REPLACED, RENOVATED, IMPROVED EQUIPMENT OR FACILITIES

Within the term of this contract, NIH may replace, renovate, or improve equipment, systems, facilities, components, and fixtures by means not associated with this contract. The Contractor

shall provide maintenance support for replaced, renovated, improved, and repaired systems facilities, components, and fixtures.

D. EQUIPMENT AND FIXTURE REPLACEMENT REQUIREMENT

When the Contractor completes work on a facility, system, or piece of equipment, that facility, or equipment shall be free of missing components or defects that would prevent it from functioning as originally intended and/or designed.

Corrective or repair and/or replacement work shall include operational checks and cleanup of the job site. When equipment and/or fixtures are replaced or repaired the contractor shall perform specific inspections, procedures, and preservation required by the manufacturer and shall verify all systems and components are operating as designed. To the greatest extent practicable, replacements shall match the existing in dimensions, finish, color, and design.

E. SUBCONTRACTOR MACHINERY AND STORAGE

Any subcontractor equipment allowed to be stored or to remain overnight on NCI property shall be kept only in designated areas and shall be the Contractor's total responsibility. The Government will not accept responsibility for loss or damage to any property of the subcontractor.

F. ENVIRONMENTAL HEALTH AND SAFETY/REGULATIONS AT THE NCI AT FREDERICK

1. The Contractor has the primary responsibility for the maintenance and perpetuation of ongoing safety programs/policies and procedures at the NCI at Frederick in accordance with applicable Federal, State and Local regulations and laws, as well as responsibility for developing new programs/policies and procedures as required. Safety programs, policies, and procedures are informed by the EHS Program Description Document. It is understood that Contracting Officer approval is not required for implementation of regulations and orders set forth by the Federal and State regulators because such regulations or orders are considered mandatory by those regulators.

2. All employees (Federal and Contractor/visitors/guests) shall comply with applicable regulations and orders, as delineated in the EHS Program Description Document and associated policies and procedures. To monitor compliance with applicable regulations and orders, the Contractor’s Safety Officer or his/her designated representative has the authority to enter all areas/facilities at the NCI at Frederick to make periodic, routine or unannounced inspections. The Contractor will attempt to resolve all deviations in safety and environmental regulations through the appropriate lines of authority. Upon inspection, deviations or discrepancies will be reported to the Laboratory Chief/Manager/Program Head for corrective action within 45 days.

   The Contractor will notify the Contracting Officer and EHS COR of the following deviations or discrepancies for appropriate action: (a) those involving willful or repeat violations; and, (b)

those that the Contractor is unable to resolve after 45 days.

In cases where the Contractor's Safety Officer judges that (a) actions require notification to or submission of a report to regulatory authorities; and/or (b) urgent, remedial, or emergency action is required, he/she is authorized to take such action, including stopping work and/or the closing down and evacuation of any area/facility at the NCI at Frederick. The Contracting Officer and EHS COR shall be informed as soon as practicable after any emergency action or notification to or submission of a report to regulatory authorities occurs.

A special notification shall be provided to the Contracting Officer and the EHS COR, within 2 working days thereafter describing the nature of the emergency or notification to or submission of a report to regulatory authorities and corrective action planned or taken.

The Contracting Officer, EHS COR, and others as designated by the Contracting Officer, shall have access to deficiencies, reports, and incident reports in the Safety Inspection and Issues Management System (SIIMS) or successor application. All incident reporting involving the following shall be maintained in SIIMS:

- Injury with loss of life, limb, or requiring hospital admission
- Report of noncompliance or incidents to regulatory authorities (e.g., NIH Office of Science Policy, OSHA, Nuclear Regulatory Commission, etc.)
- Estimated loss of government property in excess of $5,000 due to theft, fire, incident, or facility, system, or component failure that results in further damage (e.g., a failed motor causing a fire or broken pipe causing water damage).
- Significant near miss events that may have resulted in loss of human life or a building was evacuated for an identified unsafe condition.
- Incidents or issues whereby a program or laboratory is shutdown as an emergency remedial action by the EHS Director due to immediately dangerous to life and health unsafe conditions.
- Reports of noncompliance or violation from an external regulator (e.g., City of Frederick, Nuclear Regulatory Commission, etc.).

The Contracting Officer shall notify (and confirm in writing) the Contractor of any noncompliance with the provisions of this clause and corrective action to be taken. After receipt of such notice, the Contractor shall immediately take such corrective action. If the Contractor fails or refuses to comply promptly, the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action has been taken. No part of the time lost due to any such stop work order shall be the subject of the claim(s) for extension of time or for costs or damages by the Contractor.

ARTICLE H.74. NIH RETURN TO PHYSICAL WORKSPACES – CORONAVIRUS DISEASE 2019 (COVID-19)

Personnel may be requested by NIH to submit to COVID-19 testing, in accordance with NIH policy, in order to work in an NIH facility. If required by NIH policy, personnel who test positive for COVID-19 or who do not wish to submit to COVID-19 testing will not have access to or be permitted to work in an NIH facility until they have satisfied the access requirements in the NIH policy. A contract personnel's decision to opt out of COVID-19 testing will not constitute grounds for any performance delays or establish any government liability for additional costs. The Contracting Officer may determine that an excusable delay is appropriate under applicable FAR clauses (e.g., 52.242-14 (Suspension of Work), 52.242-15 (Stop-work Order), 52.249-14 (Excusable Delays), and 52.212-4(f) (Excusable Delays)) in cases where a positive test result is recorded and contract personnel must be quarantined due to an exposure to COVID-19. However, cases where a positive test result is recorded will not establish any government liability for additional costs. Testing conducted by the NIH Occupational Medical Service (OMS) falls within Privacy Act System of Records, 09-25-2015, Administration: Health Records of Employees, Visiting Scientists and Others Who Receive Medical Care through Employees Health Unit, HHS/NIH/ORS. Information regarding the Countermeasures Injury Compensation Program under the Health Resources and Services Administration is available at 1–855–266–2427 or http://www.hrsa.gov/cicp/.

Until further notice is provided by the Contracting Officer, personnel returning to work in an NIH facility are required to view a video and read written guidance prepared by the NIH to address a safe return to the physical workplace, as well as provide acknowledgement of understanding of COVID-19 worksite expectations. The contractor shall ensure that personnel complete the training as specified, shall obtain acknowledgment of the guidance from personnel, and shall provide documentation of the acknowledgement to the Contracting Officer prior to personnel returning to work in an NIH facility.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

Note: The appropriate general clause listing will be specified at the task order level

ARTICLE I.1.A GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: http://www.acquisition.gov/far/ *. HHSAR Clauses at:* http://www.hhs.gov/policies/hhsar/subpart352.html *.*

1. *FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:*

FAR CLAUSE NO.	DATE	TITLE
52.202-1	*June 2020*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*
52.203-5	*May 2014*	*Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)*
52.203-6	*June 2020*	*Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)*
52.203-7	*June 2020*	*Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)*
52.203-8	*May 2014*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-10	*May 2014*	*Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-12	*June 2020*	*Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)*
52.203-17	*June 2020*	*Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)*
52.203-19	*Jan 2017*	*Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements*
52.204-4	*May 2011*	*Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)*
52.204-10	*June 2020*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)*
52.204-13	*Oct 2018*	*System for Award Management Maintenance*

FAR CLAUSE NO.	DATE	TITLE
52.204-25	*Aug 2020*	*Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment*
52.209-6	*June 2020*	*Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $35,000)*
52.215-2	*June 2020*	*Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]*
52.215-8	*Oct 1997*	*Order of Precedence - Uniform Contract Format*
52.215-10	*Aug 2011*	*Price Reduction for Defective Certified Cost or Pricing Data (Over $750,000)*
52.215-12	*June 2020*	*Subcontractor Cost or Pricing Data (Over $750,000)*
52.215-14	*June 2020*	*Integrity of Unit Prices (Over the Simplified Acquisition Threshold)*
52.215-15	*Oct 2010*	*Pension Adjustments and Asset Reversions (Over $750,000)*
52.215-18	*Jul 2005*	*Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions*
52.215-19	*Oct 1997*	*Notification of Ownership Changes*
52.215-21	*June 2020*	*Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications*
52.215-23	*June 2020*	*Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)*
52.216-7	*Aug 2018*	*Allowable Cost and Payment*
52.216-8	*Jun 2011*	*Fixed Fee*
52.219-8	*Oct 2018*	*Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)*
52.219-9	*June 2020*	*Small Business Subcontracting Plan (Over $700,000, $1.5 million for Construction)*
52.219-16	*Jan 1999*	*Liquidated Damages - Subcontracting Plan (Over $700,000, $1.5 million for Construction)*
52.222-2	*Jul 1990*	*Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)*
52.222-3	*Jun 2003*	*Convict Labor*
52.222-21	*Apr 2015*	*Prohibition of Segregated Facilities*
52.222-26	*Sep 2016*	*Equal Opportunity*
52.222-35	*June 2020*	*Equal Opportunity for Veterans ($150,000 or more)*
52.222-36	*June 2020*	*Equal Opportunity for Workers with Disabilities*
52.222-37	*June 2020*	*Employment Reports on Veterans ($150,000 or more)*
52.222-40	*Dec 2010*	*Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)*

FAR CLAUSE NO.	DATE	TITLE
52.222-50	*Oct 2020*	*Combating Trafficking in Persons*
52.222-54	*Oct 2015*	*Employment Eligibility Verification (Over the Simplified Acquisition Threshold)*
52.223-6	*May 2001*	*Drug-Free Workplace*
52.223-18	*June 2020*	*Encouraging Contractor Policies to Ban Text Messaging While Driving*
52.225-1	*Jan 2021*	*Buy American - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.227-1	*June 2020*	*Authorization and Consent, Alternate I (Apr 1984)*
52.227-2	*June 2020*	*Notice and Assistance Regarding Patent and Copyright Infringement*
52.227-11	*May 2014*	*Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.*
52.227-14	*May 2014*	*Rights in Data - General*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*May 2014*	*Interest (Over the Simplified Acquisition Threshold)*
52.232-20	*Apr 1984*	*Limitation of Cost*
52.232-23	*May 2014*	*Assignment of Claims*
52.232-25	*Jan 2017*	*Prompt Payment, Alternate I (Feb 2002)*
52.232-33	*Oct 2018*	*Payment by Electronic Funds Transfer--System for Award Management*
52.232-39	*Jun 2013*	*Unenforceability of Unauthorized Obligations*
52.233-1	*May 2014*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award, Alternate I (Jun 1985)*
52.233-4	*Oct 2004*	*Applicable Law for Breach of Contract Claim*
52.242-1	*Apr 1984*	*Notice of Intent to Disallow Costs*
52.242-3	*May 2014*	*Penalties for Unallowable Costs (Over $700,000)*
52.242-4	*Jan 1997*	*Certification of Final Indirect Costs*
52.242-13	*Jul 1995*	*Bankruptcy (Over the Simplified Acquisition Threshold)*
52.243-2	*Aug 1987*	*Changes - Cost Reimbursement, Alternate V (Apr 1984)*
52.244-2	*June 2020*	*Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)*
52.244-5	*Dec 1996*	*Competition in Subcontracting (Over the Simplified Acquisition Threshold)*
52.244-6	*Nov 2020*	*Subcontracts for Commercial Items*
52.245-1	*Jan 2017*	*Government Property*
52.245-9	*Apr 2012*	*Use and Charges*
52.246-23	*Feb 1997*	*Limitation of Liability (Over the Simplified Acquisition Threshold)*
52.249-6	*May 2004*	*Termination (Cost-Reimbursement)*
52.249-14	*Apr 1984*	*Excusable Delays*
52.253-1	*Jan 1991*	*Computer Generated Forms*

2. *DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:*

HHSAR CLAUSE NO.	DATE	TITLE
352.203-70	*Dec 2015*	*Anti-Lobbying*
352.222-70	*Dec 2015*	*Contractor Cooperation in Equal Employment Opportunity Investigations*
352.227-70	*Dec 2015*	*Publications and Publicity*
352.233-71	*Dec 2015*	*Litigation and Claims*
352.237-75	*Dec 2015*	*Key Personnel*

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT- Rev. 06/2017].

ARTICLE I.1.B GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: http://www.acquisition.gov/far/ *. HHSAR Clauses at:* http://www.hhs.gov/policies/hhsar/subpart352.html *.*

1. *FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:*

FAR CLAUSE NO.	DATE	TITLE
52.202-1	*June 2020*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*
52.203-5	*May 2014*	*Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)*
52.203-6	*June 2020*	*Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)*
52.203-7	*June 2020*	*Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)*
52.203-8	*May 2014*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-10	*May 2014*	*Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-12	*June 2020*	*Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)*

FAR CLAUSE NO.	DATE	TITLE
52.203-17	*June 2020*	*Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)*
52.203-19	*Jan 2017*	*Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements (DEVIATION)*
52.204-4	*May 2011*	*Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)*
52.204-10	*June 2020*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)*
52.204-13	*Oct 2018*	*System for Award Management Maintenance*
52.204-25	*Aug 2020*	*Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment*
52.209-6	*June 2020*	*Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $35,000)*
52.215-2	*June 2020*	*Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]*
52.215-8	*Oct 1997*	*Order of Precedence - Uniform Contract Format*
52.215-10	*Aug 2011*	*Price Reduction for Defective Certified Cost or Pricing Data (Over $750,000)*
52.215-12	*June 2020*	*Subcontractor Cost or Pricing Data (Over $750,000)*
52.215-15	*Oct 2010*	*Pension Adjustments and Asset Reversions (Over $750,000)*
52.215-18	*Jul 2005*	*Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions*
52.215-19	*Oct 1997*	*Notification of Ownership Changes*
52.215-21	*June 2020*	*Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications*
52.215-23	*June 2020*	*Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)*
52.216-7	*Aug 2018*	*Allowable Cost and Payment*
52.216-8	*Jun 2011*	*Fixed Fee*
52.219-8	*Nov 2016*	*Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)*
52.219-9	*June 2020*	*Small Business Subcontracting Plan (Over $700,000, $1.5 million for Construction)*
52.219-16	*Jan 1999*	*Liquidated Damages - Subcontracting Plan (Over $700,000, $1.5 million for Construction)*

FAR CLAUSE NO.	DATE	TITLE
52.222-2	*Jul 1990*	*Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)*
52.222-3	*Jun 2003*	*Convict Labor*
52.222-21	*Apr 2015*	*Prohibition of Segregated Facilities*
52.222-26	*Sep 2016*	*Equal Opportunity*
52.222-35	*June 2020*	*Equal Opportunity for Veterans ($150,000 or more)*
52.222-36	*June 2020*	*Equal Opportunity for Workers with Disabilities*
52.222-37	*June 2020*	*Employment Reports on Veterans ($150,000 or more)*
52.222-40	*Dec 2010*	*Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)*
52.222-50	*Oct 2020*	*Combating Trafficking in Persons*
52.222-54	*Oct 2015*	*Employment Eligibility Verification (Over the Simplified Acquisition Threshold)*
52.223-6	*May 2001*	*Drug-Free Workplace*
52.223-18	*June 2020*	*Encouraging Contractor Policies to Ban Text Messaging While Driving*
52.225-1	*Jan 2021*	*Buy American - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.227-1	*June 2020*	*Authorization and Consent*
52.227-2	*June 2020*	*Notice and Assistance Regarding Patent and Copyright Infringement*
52.227-14	*May 2014*	*Rights in Data - General*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*May 2014*	*Interest (Over the Simplified Acquisition Threshold)*
52.232-20	*Apr 1984*	*Limitation of Cost*
52.232-23	*May 2014*	*Assignment of Claims*
52.232-25	*Jan 2017*	*Prompt Payment, Alternate I (Feb 2002)*
52.232-33	*Oct 2018*	*Payment by Electronic Funds Transfer--System for Award Management*
52.232-39	*Jun 2013*	*Unenforceability of Unauthorized Obligations*
52.233-1	*May 2014*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award, Alternate I (Jun 1985)*
52.233-4	*Oct 2004*	*Applicable Law for Breach of Contract Claim*
52.242-1	*Apr 1984*	*Notice of Intent to Disallow Costs*
52.242-3	*May 2014*	*Penalties for Unallowable Costs (Over $700,000)*
52.242-4	*Jan 1997*	*Certification of Final Indirect Costs*
52.242-13	*Jul 1995*	*Bankruptcy (Over the Simplified Acquisition Threshold)*
52.243-2	*Aug 1987*	*Changes - Cost Reimbursement, Alternate I (Apr 1984)*
52.244-2	*June 2020*	*Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)*
52.244-5	*Dec 1996*	*Competition in Subcontracting (Over the Simplified Acquisition Threshold)*
52.244-6	*Nov 2020*	*Subcontracts for Commercial Items*
52.245-1	*Jan 2017*	*Government Property*

FAR	DATE	TITLE
CLAUSE NO.		
52.245-9	*Apr 2012*	*Use and Charges*
52.246-25	*Feb 1997*	*Limitation of Liability - Services (Over the Simplified Acquisition Threshold)*
52.249-6	*May 2004*	*Termination (Cost-Reimbursement)*
52.249-14	*Apr 1984*	*Excusable Delays*
52.253-1	*Jan 1991*	*Computer Generated Forms*

2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR	DATE	TITLE
CLAUSE NO.		
352.203-70	*Dec 2015*	*Anti-Lobbying*
352.222-70	*Dec 2015*	*Contractor Cooperation in Equal Employment Opportunity Investigations*
352.227-70	*Dec 2015*	*Publications and Publicity*
352.233-71	*Dec 2015*	*Litigation and Claims*
352.237-75	*Dec 2015*	*Key Personnel*

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT SERVICE CONTRACT- Rev. 06/2017].

ARTICLE I.1.C GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: http://www.acquisition.gov/far/ *. HHSAR Clauses at:* http://www.hhs.gov/policies/hhsar/subpart352.html *.*

1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR	DATE	TITLE
CLAUSE NO.		
52.202-1	*June 2020*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*
52.203-5	*May 2014*	*Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)*
52.203-6	*June 2020*	*Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)*

FAR CLAUSE NO.	DATE	TITLE
52.203-7	*June 2020*	*Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)*
52.203-8	*May 2014*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-10	*May 2014*	*Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-12	*June 2020*	*Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)*
52.203-17	*June 2020*	*Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)*
52.203-19	*Jan 2017*	*Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements (DEVIATION)*
52.204-4	*May 2011*	*Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)*
52.204-10	*June 2020*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)*
52.204-13	*Oct 2018*	*System for Award Management Maintenance*
52.204-25	*Aug 2020*	*Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment*
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52.215-10	*Aug 2011*	*Price Reduction for Defective Certified Cost or Pricing Data (Over $750,000)*
52.215-12	*June 2020*	*Subcontractor Cost or Pricing Data (Over $750,000)*
52.215-14	*June 2020*	*Integrity of Unit Prices (Over the Simplified Acquisition Threshold)*
52.215-15	*Oct 2010*	*Pension Adjustments and Asset Reversions (Over $750,000)*
52.215-18	*Jul 2005*	*Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions*
52.215-19	*Oct 1997*	*Notification of Ownership Changes*
52.215-21	*June 2020*	*Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications*
52.219-8	*Oct 2018*	*Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)*
52.219-9	*June 2020*	*Small Business Subcontracting Plan (Over $700,000, $1.5 million for Construction)*

FAR CLAUSE NO.	DATE	TITLE
52.219-16	*Jan 1999*	*Liquidated Damages - Subcontracting Plan (Over $700,000, $1.5 million for Construction)*
52.222-3	*Jun 2003*	*Convict Labor*
52.222-21	*Apr 2015*	*Prohibition of Segregated Facilities*
52.222-26	*Sep 2016*	*Equal Opportunity*
52.222-35	*June 2020*	*Equal Opportunity for Veterans ($150,000 or more)*
52.222-36	*June 2020*	*Equal Opportunity for Workers with Disabilities*
52.222-37	*June 2020*	*Employment Reports on Veterans ($150,000 or more)*
52.222-40	*Dec 2010*	*Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)*
52.222-50	*Oct 2020*	*Combating Trafficking in Persons*
52.222-54	*Oct 2015*	*Employment Eligibility Verification (Over the Simplified Acquisition Threshold)*
52.223-6	*May 2001*	*Drug-Free Workplace*
52.223-18	*June 2020*	*Encouraging Contractor Policies to Ban Text Messaging While Driving*
52.225-1	*Jan 2021*	*Buy American - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.227-1	*June 2020*	*Authorization and Consent, Alternate I (Apr 1984)*
52.227-2	*June 2020*	*Notice and Assistance Regarding Patent and Copyright Infringement*
52.227-11	*May 2014*	*Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.*
52.227-14	*May 2014*	*Rights in Data - General*
52.229-3	*Feb 2013*	*Federal, State and Local Taxes (Over the Simplified Acquisition Threshold)*
52.232-2	*Apr 1984*	*Payments under Fixed-Price Research and Development Contracts*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*May 2014*	*Interest (Over the Simplified Acquisition Threshold)*
52.232-23	*May 2014*	*Assignment of Claims*
52.232-25	*Jan 2017*	*Prompt Payment*
52.232-33	*Jul 2013*	*Payment by Electronic Funds Transfer--System for Award Management*
52.232-39	*Jun 2013*	*Unenforceability of Unauthorized Obligations*
52.233-1	*May 2014*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award*
52.233-4	*Oct 2004*	*Applicable Law for Breach of Contract Claim*
52.242-13	*Jul 1995*	*Bankruptcy (Over the Simplified Acquisition Threshold)*
52.243-1	*Aug 1987*	*Changes - Fixed Price, Alternate V (Apr 1984)*
52.244-6	*Nov 2020*	*Subcontracts for Commercial Items*
52.246-23	*Feb 1997*	*Limitation of Liability (Over the Simplified Acquisition Threshold)*
52.249-2	*Apr 2012*	*Termination for the Convenience of the Government (Fixed-Price)*

FAR CLAUSE NO.	DATE	TITLE
52.249-9	*Apr 1984*	*Default (Fixed-Price Research and Development)(Over the Simplified Acquisition Threshold)*
52.253-1	*Jan 1991*	*Computer Generated Forms*

2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.203-70	*Dec 2015*	*Anti-Lobbying*
352.222-70	*Dec 2015*	*Contractor Cooperation in Equal Employment Opportunity Investigations*
352.227-70	*Dec 2015*	*Publications and Publicity*
352.237-75	*Dec 2015*	*Key Personnel*

[End of GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT- Rev. 06/2017].

ARTICLE I.1.D GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE SERVICE CONTRACT

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: http://www.acquisition.gov/far/ *. HHSAR Clauses at:* http://www.hhs.gov/policies/hhsar/subpart352.html .

1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	*June 2020*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*
52.203-5	*May 2014*	*Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)*
52.203-6	*June 2020*	*Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)*
52.203-7	*June 2020*	*Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)*

FAR CLAUSE NO.	DATE	TITLE
52.203-8	*May 2014*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-10	*May 2014*	*Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-12	*June 2020*	*Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)*
52.203-17	*June 2020*	*Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)*
52.203-19	*Jan 2017*	*Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements (DEVIATION)*
52.204-4	*May 2011*	*Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)*
52.204-10	*June 2020*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)*
52.204-13	*Oct 2018*	*System for Award Management Maintenance*
52.204-25	*Aug 2020*	*Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment*
52.209-6	*June 2020*	*Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $35,000)*
52.215-2	*June 2020*	*Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]*
52.215-8	*Oct 1997*	*Order of Precedence - Uniform Contract Format*
52.215-10	*Aug 2011*	*Price Reduction for Defective Certified Cost or Pricing Data (Over $750,000)*
52.215-12	*June 2020*	*Subcontractor Cost or Pricing Data (Over $750,000)*
52.215-15	*Oct 2010*	*Pension Adjustments and Asset Reversions (Over $750,000)*
52.215-18	*Jul 2005*	*Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions*
52.215-19	*Oct 1997*	*Notification of Ownership Changes*
52.215-21	*June 2020*	*Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications*
52.219-8	*Oct 2018*	*Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)*
52.219-9	*June 2020*	*Small Business Subcontracting Plan (Over $700,000, $1.5 million for Construction)*
52.219-16	*Jan 1999*	*Liquidated Damages - Subcontracting Plan (Over $700,000, $1.5 million for Construction)*

FAR CLAUSE NO.	DATE	TITLE
52.222-3	*Jun 2003*	*Convict Labor*
52.222-21	*Apr 2015*	*Prohibition of Segregated Facilities*
52.222-26	*Sep 2016*	*Equal Opportunity*
52.222-35	*June 2020*	*Equal Opportunity for Veterans ($150,000 or more)*
52.222-36	*June 2020*	*Equal Opportunity for Workers with Disabilities*
52.222-37	*June 2020*	*Employment Reports on Veterans ($150,000 or more)*
52.222-40	*Dec 2010*	*Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)*
52.222-50	*Oct 2020*	*Combating Trafficking in Persons*
52.222-54	*Oct 2015*	*Employment Eligibility Verification (Over the Simplified Acquisition Threshold)*
52.223-6	*May 2001*	*Drug-Free Workplace*
52.223-18	*June 2020*	*Encouraging Contractor Policies to Ban Text Messaging While Driving*
52.225-1	*Jan 2021*	*Buy American - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.227-1	*June 2020*	*Authorization and Consent*
52.227-2	*June 2020*	*Notice and Assistance Regarding Patent and Copyright Infringement*
52.229-3	*Feb 2013*	*Federal, State and Local Taxes (Over the Simplified Acquisition Threshold)*
52.232-1	*Apr 1984*	*Payments*
52.232-8	*Feb 2002*	*Discounts for Prompt Payment*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-11	*Apr 1984*	*Extras*
52.232-17	*May 2014*	*Interest (Over the Simplified Acquisition Threshold)*
52.232-23	*May 2014*	*Assignment of Claims*
52.232-25	*Jan 2017*	*Prompt Payment*
52.232-33	*Oct 2018*	*Payment by Electronic Funds Transfer--System for Award Management*
52.232-39	*Jun 2013*	*Unenforceability of Unauthorized Obligations*
52.233-1	*May 2014*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award*
52.233-4	*Oct 2004*	*Applicable Law for Breach of Contract Claim*
52.242-13	*Jul 1995*	*Bankruptcy (Over the Simplified Acquisition Threshold)*
52.243-1	*Aug 1987*	*Changes - Fixed-Price, Alternate I (Apr 1984)*
52.244-6	*Nov 2020*	*Subcontracts for Commercial Items*
52.246-25	*Feb 1997*	*Limitation of Liability - Services (Over the Simplified Acquisition Threshold)*
52.249-4	*Apr 1984*	*Termination for Convenience of the Government (Services) (Short Form)*
52.249-8	*Apr 1984*	*Default (Fixed-Price Supply and Service)(Over the Simplified Acquisition Threshold)*
52.253-1	*Jan 1991*	*Computer Generated Forms*

2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR	DATE	TITLE
CLAUSE NO.		
352.203-70	*Dec 2015*	*Anti-Lobbying*
352.222-70	*Dec 2015*	*Contractor Cooperation in Equal Employment Opportunity Investigations*
352.227-70	*Dec 2015*	*Publications and Publicity*
352.237-75	*Dec 2015*	*Key Personnel*

[End of GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE SERVICE CONTRACT- Rev. 06/2017].

ARTICLE I.2 AUTHORIZED SUBSTITUTIONS OF CLAUSES

ARTICLE I.1.A through I.1.D of this SECTION are hereby modified as specified:

A. FAR Clause **52.215-23, Limitations on Pass-Through Charges** (June 2020), is added.
(Applicable to ARTICLE I.1.A and I.1.B)

B. FAR Clause **52.225-1, Buy American--Supplies** (Jan 2021) is deleted in its entirety and FAR Clause **52.225-5, Trade Agreements** (August 2018) is substituted therefor.
(Applicable to ARTICLE I.1.A through I.1.D)

C. FAR Clause **52.227-14, Rights in Data-General** (May 2014) is deleted in its entirety.
(Applicable to ARTICLE I.1.A through I.1.C)

D. FAR Clause **52.229-3, Federal, State and Local Taxes** (February 2013), is deleted in its entirety, and FAR Clause **52.229-6, Taxes--Foreign Fixed-Price Contracts** (February 2013) is substituted therefor.
(Applicable to ARTICLE I.1.C and I.1.D)

E. FAR Clause 52.232-20, Limitation Of Cost (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. [NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]
(Applicable to ARTICLE I.1.A and I.1.B)

F. **Alternate I** (February 2002), of FAR Clause **52.232-25, Prompt Payment** (Jan 2017) is deleted.
(Applicable to ARTICLE I.1.A and I.1.B)

G. **Alternate I** (April 1984) of FAR Clause **52.243-1, Changes, Fixed Price** (August 1987), is hereby deleted in its entirety and **Alternate II** (April 1984) of FAR Clause **52.243-1, Changes, Fixed Price** (August 1987), is substituted therefor.
(Applicable to ARTICLE I.1.D)

ARTICLE I.3 ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

A. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (June 2020).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (June 2020).

   ".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf

3. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (January 2011).

4. FAR Clause **52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts** (October 2016)

5. FAR Clause **52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment** (Aug 2020).

6. FAR Clause **52.208-8, Required Sources for Helium and Helium Usage Data** (Aug 2018).

7. FAR Clause **52.208-9, Contractor Use of Mandatory Sources of Supply or Services** (May 2014).

8. FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (November 2015).

9. FAR Clause **52.210-1, Market Research** (June 2020).

10. FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).

11. FAR Clause **52.219-28, Post-Award Small Business Program Representation** (Nov 2020).

12. FAR Clause **52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation - General** (May 2018).

13. FAR Clause **52.222-26, Equal Opportunity** (September 2016)

14. FAR Clause **52.222-29, Notification of Visa Denial** (April 2015).

15. FAR Clause **52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts** (September 2013).

16. FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).

17. FAR Clause **52.223-5, Pollution Prevention and Right-to-Know Information** (May 2011).

    Alternate I (May 2011) is applicable to this contract.

    Alternate II (May 2011) is applicable to this contract.

18. FAR Clause **52.223-10, Waste Reduction Program** (May 2011).

19. FAR Clause **52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners** (June 2016).

20. FAR Clause **52.223-13 Acquisition of EPEAT®-Registered Imaging Equipment** (June 2014)

    Alternate I (Oct 2015) is not applicable to this contract.

21. FAR Clause **52.223-14 Acquisition of EPEAT®-Registered Televisions** (June 2014)

    Alternate I (June 2014) is not applicable to this contract.

22. FAR Clause **52.223-15, Energy Efficiency in Energy-Consuming Products** (May 2020).

23. FAR Clause **52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products** (October 2015).

    Alternate I (June 2014) is not applicable to this contract.

24. FAR Clause **52.223-17, Affirmative Procurement of EPA-designated Items in Service and Construction Contracts** (Aug 2018).

25. FAR Clause **52.223-19, Compliance with Environmental Management Sys**tems (May 2011).

26. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

27. FAR Clause **52.224-2, Privacy Act** (April 1984).

28. FAR Clause **52.225-8, Duty-Free Entry** (October 2010).

29. FAR Clause **52.225-10, Notice of Buy American Requirement-Construction Materials** (May 2014).

30. FAR Clause **52.227-1, Authorization and Consent, Alternate I** (April 1984).

31. FAR Clause **52.227-13, Patent Rights--Ownership by the Government** (December 2007).

32. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

33. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

34. FAR Clause **52.227-18, Rights in Data--Existing Works** (December 2007).

35. FAR Clause **52.227-19, Commercial Computer Software License** (December 2007).

36. FAR Clause **52.228-5, Insurance - Work on a Government Installation** (January 1997).

37. FAR Clause **52.229-8, Taxes-Foreign Cost-Reimbursement Contracts** (March 1990).

38. FAR Clause **52.230-2, Cost Accounting Standards** (June 2020).

39. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).

40. FAR Clause **52.236-13, Accident Prevention** (November 1991), with **Alternate I** (November 1991).

41. FAR Clause **52.237-2, Protection of Government Buildings, Equipment and Vegetation** (April 1984).

42. FAR Clause **52.237-3, Continuity of Services** (January 1991).

43. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

44. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2014).

45. FAR Clause **52.242-4, Certification of Final Indirect Costs** (January 1997).

46. FAR Clause, **52.243-1, Changes- Fixed Price, Alternate V** (April 1984).

47. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).

48. FAR Clause **52.244-5, Competition in Subcontracting** (December 1996).

49. FAR Clause **52.245-1, Government Property** (Jan 2017)

50. FAR Clause **52.245-9 Use and Charges** (April 2012).

51. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).

52. FAR Clause **52.247-64, Preference for Privately Owned U.S. Flag Commercial Vessels** (February 2006).

53. FAR Clause **52.251-1, Government Supply Sources** (April 2012).

B. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.211-2, Conference Sponsorship Request and Conference Materials Disclaimer** (December 2015)

2. HHSAR Clause **352.211-3, Paperwork Reduction Act** (December 2015)

3. HHSAR Clause **352.223-70, Safety and Health** (December 2015)

4. HHSAR Clause **352.231-70, Salary Rate Limitation** (December 2015)

   Note : *The Salary Rate Limitation is at the Executive Level II Rate.*

   See the following website for Executive Schedule rates of pay: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/ .

   (*For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted* .)

5. HHSAR Clause **352.237-71, Crime Control Act of 1990--Reporting of Child Abuse** (December 2015).

ARTICLE I.4 ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

A. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.204-21, Basic Safeguarding of Covered Contractor Information Systems** (June 2016)

a. *Definitions* . As used in this clause--

"Covered contractor information system" means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

"Federal contract information" means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

"Information" means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

"Information system" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

"Safeguarding" means measures or controls that are prescribed to protect information systems.

b. Safeguarding requirements and procedures.

1. The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements

and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

i. Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

ii. Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

iii. Verify and control/limit connections to and use of external information systems.

iv. Control information posted or processed on publicly accessible information systems.

v. Identify information system users, processes acting on behalf of users, or devices.

vi. Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

vii. Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

viii. Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

ix. Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

x. Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

xi. Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

xii. Identify, report, and correct information and information system flaws in a timely manner.

xiii. Provide protection from malicious code at appropriate locations within organizational information systems.

xiv. Update malicious code protection mechanisms when new releases are available.

xv. Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

2. *Other requirements.* This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

c. *Subcontracts*. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

2. FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (October 2018)

As prescribed in 9.104-7(c), insert the following clause:

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the System for Award Management via https://www.sam.gov.

(b) As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIIS consist of two segments—

(1) The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by—

(i) Government personnel and authorized users performing business on behalf of the Government; or

(ii) The Contractor, when viewing data on itself; and
(2) The publicly-available segment, to which all data in the non-public segment of FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for--

(i) Past performance reviews required by subpart 42.15;

(ii) Information that was entered prior to April 15, 2011; or

(iii) Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

(c) The Contractor will receive notification when the Government posts new information to the Contractor's record.

(1) If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIIS.

(2) The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

(3) As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

(d) Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(End of clause)

3. FAR Clause **52.216-18, Ordering** (Aug 2020).

    a. Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from June 26, 2019 through June 25, 2021 .

b. All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.
c. A delivery order or task order is considered "issued" when –
    i. If sent by mail (includes transmittal by U.S. mail or private delivery service), the Government deposits the order in the mail
    ii. If sent by fax, the Government transmits the order to the Contractor's fax number; or
    iii. If sent electronically, the Government either—
        a. Posts a copy of the delivery order or task order to a Government document access system, and notice is sent to the Contractor; or
        b. Distributes the delivery order or task order via email to the Contractor's email address.
d. Orders may be issued by methods other than those enumerated in this clause only if authorized in the contract.

(End of clause)

4. FAR Clause **52.216-19, Order Limitations** (October 1995)
    a. **Minimum Order**. When the Government requires supplies or services covered by this contract in an amount of less than $5,000, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.
    b. **Maximum Order.** The Contractor is not obligated to honor--
        i. Any order for a single item in excess of [redacted].
        ii. Any order for a combination of items in excess of [redacted] or
        iii. A series of orders from the same ordering office within 365 calendar days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.
    c. If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.
    d. Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 30 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

5. FAR Clause **52.216-22, Indefinite Quantity** (October 1995)

a. This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.
b. Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."
c. Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.
d. Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after June 24, 2025.

(End of clause)

6. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

a. The Government may extend the term of this contract by written notice to the Contractor within 10 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.
b. If the Government exercises this option, the extended contract shall be considered to include this option clause.
c. The total duration of this contract's ordering period, including the exercise of any optional ordering periods under this clause, shall not exceed 60 MONTHS.

7. FAR Clause **52.223-7, Notice of Radioactive Materials** (January 1997)

a. The Contractor shall notify the Contracting Officer or designee, in writing, ten (10) days prior to completion of any servicing required by this contract of, items containing either (1) radioactive material requiring specific licensing under the regulations issued pursuant to the Atomic Energy Act of 1954, as amended, as set forth in Title 10 of the Code of Federal Regulations, in effect on the date of this contract, or (2) other radioactive material not requiring specific licensing in which the specific activity is greater than 0.002 microcuries per gram or the activity per item equals or exceeds 0.01 microcuries. Such notice shall specify the part or parts of the items which contain radioactive materials, a description of the materials, the name and activity of the isotope, the manufacturer of the materials, and any other information known to the Contractor which will put users of the

items on notice as to the hazards involved (OMB No. 9000-0107).

b. If there has been no change affecting the quantity of activity, or the characteristics and composition of the radioactive material from deliveries under this contract or prior contracts, the Contractor may request that the Contracting Officer or designee waive the notice requirement in paragraph (a) of this clause. Any such request shall-

    i. Be submitted in writing;
    ii. State that the quantity of activity, characteristics, and composition of the radioactive material have not changed; and
    iii. Cite the contract number on which the prior notification was submitted and the contracting office to which it was submitted.

c. All items, parts, or subassemblies which contain radioactive materials in which the specific activity is greater than 0.002 microcuries per gram or activity per item equals or exceeds 0.01 microcuries, and all containers in which such items, parts or subassemblies are delivered to the Government shall be clearly marked and labeled as required by the latest revision of MIL-STD 129 in effect on the date of the contract.

d. This clause, including this paragraph (d), shall be inserted in all subcontracts for radioactive materials meeting the criteria in paragraph (a) of this clause.

8. FAR Clause **52.223-9, Estimate of Percentage of Recovered Material Content for EPA Designated Item**s (May 2008)

a. *Definitions.* As used in this clause --

Postconsumer material means a material or finished product that has served its intended use and has been discarded for disposal or recovery, having completed its life as a consumer item. Postconsumer material is a part of the broader category of "recovered material.''

Recovered material means waste materials and by-products recovered or diverted from solid waste, but the term does not include those materials and by-products generated from, and commonly reused within, an original manufacturing process.

b. The Contractor, on completion of this contract, shall--
    i. Estimate the percentage of the total recovered material content for EPA-designated item(s) delivered and/or used in contract performance, including, if applicable, the percentage of post-consumer material content; and

ii. Submit this estimate to the Contracting Officer and FFRDC-Technical and Scientific Support COR.

9. FAR Clause **52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons** (June 2016)

a. Definitions. As used in this clause--

"Global warming potential" means how much a given mass of a chemical contributes to global warming over a given time period compared to the same mass of carbon dioxide. Carbon Dioxide's global warming potential is defined as 1.0.

"High global warming potential hydrofluorocarbons" means any hydrofluorocarbons in a particular end use for which EPA's Significant New Alternatives Policy (SNAP) program has identified other acceptable alternatives that have lower global warming potential. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables of alternatives available at (http://www.epa.gov/snap/).

"Hydrofluorocarbons" means compounds that only contain hydrogen, fluorine, and carbon.

"Ozone-depleting substance" means any substance the Environmental Protection Agency designates in 40 CFR Part 82 as--

i. Class I, including, but not limited to, chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform; or
ii. Class II, including, but not limited to hydrochlorofluorocarbons.

b. The Contractor shall label products which contain or are manufactured with ozone-depleting substances in the manner and to the extent required by 42 U.S.C. 7671j (b), (c), (d), and (e) and 40 CFR Part 82, Subpart E, as follows:

Warning- Contains (or manufactured with, if applicable) *_____, a substance(s) which harm(s) public health and environment by destroying ozone in the upper atmosphere.

* The Contractor shall insert the name of the substance(s).

c. *Reporting*. For equipment and appliances that normally each contain 50 or more pounds of hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons, the Contractor shall-
    i. Track on an annual basis, between October 1 and September 30, the amount in pounds of hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons contained in the equipment and appliances delivered to the Government under this contract by-
        a. Type of hydrofluorocarbon (e.g., HFC-134a, HFC-125, R-410A, R-404A, etc.);
        b. Contract number; and
        c. Equipment/appliance;
    ii. Report that information to the Contracting Officer for FY16 and to www.sam.gov , for FY17 and after00
        a. Annually by November 30 of each year during contract performance; and
        b. At the end of contract performance.

d. The Contractor shall refer to EPA's SNAP program (available at http://www.epa.gov/snap) to identify alternatives. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables available at http://www.epa.gov/snap

10. FAR Clause **52.223-20, Aerosols** (June 2016)

a. *Definitions*. As used in this clause--

"Global warming potential" means how much a given mass of a chemical contributes to global warming over a given time period compared to the same mass of carbon dioxide. Carbon dioxide's global warming potential is defined as 1.0.

"High global warming potential hydrofluorocarbons" means any hydrofluorocarbons in a particular end use for which EPA's Significant New Alternatives Policy (SNAP) program has identified other acceptable alternatives that have lower global warming potential. The SNAP list of alternatives is found at 40 CFR part 82, subpart G. with supplemental tables of alternatives available at http://www.epa.gov/snap/).

"Hydrofluorocarbons" means compounds that contain only hydrogen, fluorine, and carbon.

b. Unless otherwise specified in the contract, the Contractor shall reduce its use, release, or emissions of high global warming potential hydrofluorocarbons, when feasible, from aerosol propellants or solvents under this contract. When determining feasibility of using a particular alternative, the Contractor shall consider environmental, technical, and economic factors such as--

i. In-use emission rates, energy efficiency;

ii. Safety, such as flammability or toxicity;

iii. Ability to meet technical performance requirements; and

iv. Commercial availability at a reasonable cost.

c. The Contractor shall refer to EPA's SNAP program to identify alternatives. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables available at http://www.epa.gov/snap/

11. FAR Clause **52.223-21, Foams** (June 2016)

a. *Definitions.* As used in this clause--

"Global warming potential" means how much a given mass of a chemical contributes to global warming over a given time period compared to the same mass of carbon dioxide. Carbon dioxide's global warming potential is defined as 1.0.

"High global warming potential hydrofluorocarbons" means any hydrofluorocarbons in a particular end use for which EPA's Significant New Alternatives Policy (SNAP) program has identified other acceptable alternatives that have lower global warming potential. The SNAP list of alternatives is found at 40 CFR part 82, subpart G. with supplemental tables of alternatives available at http://www.epa.gov/snap/).

"Hydrofluorocarbons" means compounds that contain only hydrogen, fluorine, and carbon.

b. Unless otherwise specified in the contract, the Contractor shall reduce its use, release, and emissions of high global warming potential hydrofluorocarbons and refrigerant blends containing hydrofluorocarbons, when feasible, from foam blowing agents, under this contract. When determining feasibility of using a particular alternative, the Contractor shall consider environmental, technical, and economic factors such as--

i. In-use emission rates, energy efficiency, and safety;

ii. Ability to meet performance requirements; and;

iii. Commercial availability at a reasonable cost.

c. The Contractor shall refer to EPA's SNAP program to identify alternatives. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables available at http://www.epa.gov/snap/.

12. FAR Clause **52.226-6, Promoting Excess Food Donation to Nonprofit Organizations** (June 2020)

(a) Definitions. As used in this clause-

Apparently wholesome food means food that meets all quality and labeling standards imposed by Federal, State, and local laws and regulations even though the food may not be readily marketable due to appearance, age, freshness, grade, size, surplus, or other conditions.

Excess food means food that-

(1) Is not required to meet the needs of the executive agencies; and

(2) Would otherwise be discarded.

Food-insecure means inconsistent access to sufficient, safe, and nutritious food.

Nonprofit organization means any organization that is—

(1) Described in section 501(c) of the Internal Revenue Code of 1986; and

(2) Exempt from tax under section 501(a) of that Code.

(b) In accordance with the Federal Food Donation Act of 2008 (42 U.S.C. 1792), the Contractor is encouraged, to the maximum extent practicable and safe, to donate excess, apparently wholesome food to nonprofit organizations that provide assistance to food-insecure people in the United States.

(c) Costs. (1) The Contractor, including any subcontractors, shall assume the responsibility for all the costs and the logistical support to collect, transport, maintain the safety of, or distribute the excess, apparently wholesome food to the nonprofit organization(s) that provides assistance to food-insecure people.

(2) The Contractor will not be reimbursed for any costs incurred or associated with the donation of excess foods. Any costs incurred for excess food donations are unallowable.

(d) Liability. The Government and the Contractor, including any subcontractors, shall be exempt from civil and criminal liability to the extent provided under the Bill Emerson Good Samaritan Food Donation Act (42 U.S.C. 1791). Nothing in this clause shall be construed to supersede State or local health regulations (subsection (f) of 42 U.S. C. 1791).

(e) Subcontracts. The Contractor shall insert this clause in all contracts, task orders, delivery orders, purchase orders, and other similar instruments that exceed the threshold specified in Federal Acquisition Regulation 26.404 on the date of subcontract award with its subcontractors or suppliers, at any tier, who will perform, under this contract, the provision, service, or sale of food in the United States.

(End of clause)

13. FAR Clause **52.228-7 -- Insurance -- Liability to Third Persons**.

Insurance -- Liability to Third Persons (Mar 1996)

(a)

(1) Except as provided in subparagraph (a)(2) of this clause, the Contractor shall provide and maintain workers' compensation, employer's liability, comprehensive general liability (bodily injury), comprehensive automobile liability (bodily injury and property damage) insurance, and such other insurance as the Contracting Officer may require under this contract.

(2) The Contractor may, with the approval of the Contracting Officer, maintain a self-insurance program; provided that, with respect to workers' compensation, the Contractor is qualified pursuant to statutory authority.

(3) All insurance required by this paragraph shall be in a form and amount and for those periods as the Contracting Officer may require or approve and with insurers approved by the Contracting Officer.

(b) The Contractor agrees to submit for the Contracting Officer's approval, to the extent and in the manner required by the Contracting Officer, any other insurance that is maintained by the Contractor in connection with the performance of this contract and for which the Contractor seeks reimbursement.

(c) The Contractor shall be reimbursed --

(1) For that portion --

(i) Of the reasonable cost of insurance allocable to this contract; and
(ii) Required or approved under this clause; and

(2) For certain liabilities (and expenses incidental to such liabilities) to third persons not compensated by insurance or otherwise without regard to and as an exception to the limitation of cost or the limitation of funds clause of this contract. These liabilities must arise out of the performance of this contract, whether or not caused by the negligence of the Contractor or of the Contractor's agents, servants, or employees, and must be represented by final judgments or settlements approved in writing by the Government. These liabilities are for --

(i) Loss of or damage to property (other than property owned, occupied, or used by the Contractor, rented to the Contractor, or in the care, custody, or control of the Contractor); or

(ii) Death or bodily injury.

(d) The Government's liability under paragraph (c) of this clause is subject to the availability of appropriated funds at the time a contingency occurs. Nothing in this contract shall be construed as implying that the Congress will, at a later date, appropriate funds sufficient to meet deficiencies.

(e) The Contractor shall not be reimbursed for liabilities (and expenses incidental to such liabilities) --

(1) For which the Contractor is otherwise responsible under the express terms of any clause specified in the Schedule or elsewhere in the contract;

(2) For which the Contractor has failed to insure or to maintain insurance as required by the Contracting Officer; or

(3) That result from willful misconduct or lack of good faith on the part of any of the Contractor's directors, officers, managers, superintendents, or other representatives who have supervision or direction of --

(i) All or substantially all of the Contractor's business;
(ii) All or substantially all of the Contractor's operations at any one plant or separate location in which this contract is being performed; or
(iii) A separate and complete major industrial operation in connection with the performance of this contract.

(f) The provisions of paragraph (e) of this clause shall not restrict the right of the Contractor to be reimbursed for the cost of insurance maintained by the Contractor in connection with the performance of this contract, other than insurance required in accordance with this clause; provided, that such cost is allowable under the Allowable Cost and Payment clause of this contract.

(g) If any suit or action is filed or any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, and the risk of which is then uninsured or is insured for less than the amount claimed, the Contractor shall --

(1) Immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received;

(2) Authorize Government representatives to collaborate with counsel for the insurance carrier in settling or defending the claim when the amount of the liability claimed exceeds the amount of coverage; and

(3) Authorize Government representatives to settle or defend the claim and to represent the Contractor in or to take charge of any litigation, if required by the Government, when the liability is not insured or covered by bond. The Contractor may, at its own expense, be associated with the Government representatives in any such claim or litigation.

(End of Clause)

14. Far Clause **52.232-12, Advance Payments** (May 2001), with **Alternate I** (Apr 1984), **Alternate II** (May 2001), and **Alternate IV** (APR 1984)

(a) Requirements for payment. Advance payments will be made under this contract (1) upon submission of properly certified invoices or vouchers by the Contractor, and approval by the administering office, National Cancer Institute, or (2) under a letter of credit. The amount of the invoice or voucher submitted plus all advance payments previously approved shall not exceed [redacted]. If a letter of credit is used, the Contractor shall withdraw cash only when needed for disbursements acceptable under this contract and report cash disbursements and balances as required by the administering office. The Contractor shall apply terms similar to this clause to any advance payments to subcontractors.

(b) Special account. Until (1) the Contractor has liquidated all advance payments made under the contract and related interest charges and (2) the administering office has approved in writing the release of any funds due and payable to the Contractor, all advance payments and other payments under this contract shall be made by check payable to the Contractor marked for deposit only in the Contractor's special account with the [redacted] None of the funds in the special account shall be mingled with other funds of the Contractor. Withdrawals from the special account may be made only by check of the Contractor countersigned by the Contracting Officer or a Government countersigning agent designated in writing by the Contracting Officer.

However, for this contract, countersignature on behalf of the Government will not be required unless it is determined necessary by the administering office.

(c) Use of funds. The Contractor shall withdraw funds from the special account only to pay for allowable costs as prescribed by the ALLOWABLE COST AND PAYMENT clause of this contract. Payment for any other types of expenses shall be approved in writing by the administering office.

(d) Repayment to the Government. At any time, the Contractor may repay all or any part of the funds advanced by the Government. Whenever requested in writing to do so by the administering office, the Contractor shall repay to the Government any part of unliquidated advance payments considered by the administering office to exceed the Contractor's current requirements or the amount specified in paragraph (a) of this clause. If the Contractor fails to repay the amount requested by the administering office, all or any part of the unliquidated advance payments may be withdrawn from the special account by check signed by only the countersigning agent and applied to reduction of the unliquidated advance payments under this contract.

(e) Maximum payment. When the sum of all unliquidated advance payments, unpaid interest charges, and other payments equal the total estimated cost of [redacted] (not including fixed-fee, if any) for the work under this contract, the Government shall withhold further payments to the Contractor. Upon completion or termination of the contract, the Government shall deduct from the amount due to the Contractor all unliquidated advance payments and interest charges payable. The Contractor shall pay any deficiency to the Government upon demand. For purposes of this paragraph, the estimated cost shall be considered to be the stated estimated cost, less any subsequent reductions of the estimated cost, plus any increases in the estimated costs that do not, in the aggregate, exceed $6.6B. The estimated cost shall include, without limitation, any reimbursable cost (as estimated by the Contracting Officer) incident to a termination for the convenience of the Government. Any payments withheld under this paragraph shall be applied to reduce the unliquidated advance payments. If full liquidation has been made, payments under the contract shall resume.

(f) Interest. No interest shall be charged to the prime Contractor for advance payments except for interest charged during a period of default. The terms of this paragraph concerning interest charges for advance payments shall not apply to the prime Contractor.

(1) The Contractor shall pay interest to the Government on the daily unliquidated advance payments at the daily rate specified in paragraph (f)(3) of this clause. Interest shall be computed at the end of each calendar month for the actual number of days involved. For the purpose of computing the interest charge, the following shall be observed:

(i) Advance payments shall be considered as increasing the unliquidated balance as of the date of the advance payment check.

(ii) Repayments by Contractor check shall be considered as decreasing the unliquidated balance as of the date on which the check is received by the Government authority designated by the Contracting Officer.

(iii) Liquidations by deductions from payments to the Contractor shall be considered as decreasing the unliquidated balance as of the dates on which the Contractor presents to the Contracting Officer full and accurate data for the preparation of each voucher. Credits resulting from these deductions shall be made upon the approval of the reimbursement vouchers by the Disbursing Officer, based upon the Contracting Officer's certification of the applicable dates.

(2) Interest charges resulting from the monthly computation shall be deducted from any payments on account of the fixed-fee due to the Contractor. If the accrued interest exceeds the payment due, any excess interest shall be carried forward and deducted from subsequent payments of the contract price or fixed-fee. Interest carried forward shall not be compounded. Interest on advance payments shall cease to accrue upon (i)satisfactory completion or (ii)termination of the contract for the convenience of the Government. The Contractor shall charge interest on advance payments to subcontractors in the manner described above and credit the interest to the Government. Interest need not be charged on advance payments to nonprofit educational or research subcontractors for experimental, developmental, or research work.

(3) If interest is required under the contract, the Contracting Officer shall determine a daily interest rate based on the higher of (i)the published prime rate of the financial institution (depository) in which the special account is established or (ii)the rate established by the Secretary of the Treasury under Pub.L.92-41 (50 U.S.C. App.1215(b)(2)). The Contracting Officer shall revise the daily interest rate during the contract period in keeping with any changes in the cited interest rates.

(4) If the full amount of interest charged under this paragraph has not been paid by deduction or otherwise upon completion or termination of this contract, the Contractor shall pay the remaining interest to the Government on demand.

(g) Financial institution agreement. Before an advance payment is made under this contract, the Contractor shall transmit to the administering office, in the form prescribed by the administering office, an agreement in triplicate from the financial institution in which the special account is established, clearly setting forth the special character of the account and the responsibilities of the financial institution under the account. The Contractor shall select a financial institution that is a member bank of the Federal Reserve System, an "insured" bank within the meaning of the Federal Deposit Insurance Corporation Act (12 U.S.C.1811), or a credit union insured by the National Credit Union Administration.

(h) Lien on special bank account. The Government shall have a lien upon any balance in the special account paramount to all other liens. The Government lien shall secure the repayment of any advance payments made under this contract and any related interest charges.

(i) Lien on property under contract.

(1) All advance payments under this contract, together with interest charges, shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, on the supplies or other things covered by this contract and on material and other property acquired for or allocated to the performance of this contract, except to the extent that the Government by virtue of any other terms of this contract, or otherwise, shall have valid title to the supplies, materials, or other property as against other creditors of the Contractor.

(2) The Contractor shall identify, by marking or segregation, all property that is subject to a lien in favor of the Government by virtue of any terms of this contract in such a way as to indicate that it is subject to a lien and that it has been acquired for or allocated to performing this contract. If, for any reason, the supplies, materials, or other property are not identified by marking or segregation, the Government shall be considered to have a lien to the extent of the Government's interest under this contract on any mass of property with which the supplies, materials, or other property are commingled. The Contractor shall maintain adequate accounting control over the property on its books and records.

(3) If, at any time during the progress of the work on the contract, it becomes necessary to deliver to a third person any items or materials on which the Government has a lien, the Contractor shall notify the third person of the lien and shall obtain from the third person a receipt in duplicate acknowledging the existence of the lien. The Contractor shall provide a copy of each receipt to the Contracting Officer.

(4) If, under the termination clause, the Contracting Officer authorizes the Contractor to sell or retain termination inventory, the approval shall constitute a release of the Government's lien to the extent that-

(i) The termination inventory is sold or retained; and
(ii) The sale proceeds or retention credits are applied to reduce any outstanding advance payments.

(j) Insurance.

(1) The Contractor shall maintain with responsible insurance carriers-

(i) Insurance on plant and equipment against fire and other hazards, to the extent that similar properties are usually insured by others operating plants and properties of similar character in the same general locality;
(ii) Adequate insurance against liability on account of damage to persons or property; and
(iii) Adequate insurance under all applicable workers' compensation laws.

(2) Until work under this contract has been completed and all advance payments made under the contract have been liquidated, the Contractor shall-

(i) Maintain this insurance;

(ii) Maintain adequate insurance on any materials, parts, assemblies, subassemblies, supplies, equipment, and other property acquired for or allocable to this contract and subject to the Government lien under paragraph (i) of this clause; and
(iii) Furnish any evidence with respect to its insurance that the administering office may require.

(k) Default.

(1) If any of the following events occurs, the Government may, by written notice to the Contractor, withhold further withdrawals from the special account and further payments on this contract:

(i) Termination of this contract for a fault of the Contractor.
(ii) A finding by the administering office that the Contractor has failed to-
(A) Observe any of the conditions of the advance payment terms;
(B) Comply with any material term of this contract;
(C) Make progress or maintain a financial condition adequate for performance of this contract;
(D) Limit inventory allocated to this contract to reasonable requirements; or
(E) Avoid delinquency in payment of taxes or of the costs of performing this contract in the ordinary course of business.
(iii) The appointment of a trustee, receiver, or liquidator for all or a substantial part of the Contractor's property, or the institution of proceedings by or against the Contractor for bankruptcy, reorganization, arrangement, or liquidation.
(iv) The service of any writ of attachment, levy of execution, or commencement of garnishment proceedings concerning the special account.
(v) The commission of an act of bankruptcy.

(2) If any of the events described in paragraph (k)(1) of this clause continue for 30 days after the written notice to the Contractor, the Government may take any of the following additional actions:

(i) Withdraw by checks payable to the Treasurer of the United States, signed only by the countersigning agency, all or any part of the balance in the special account and apply the amounts to reduce outstanding advance payments and any other claims of the Government against the Contractor.
(ii) Charge interest, in the manner prescribed in paragraph (f) of this clause, on outstanding advance payments during the period of any event described in paragraph (k)(1) of this clause.
(iii) Demand immediate repayment by the Contractor of the unliquidated balance of advance payments.
(iv) Take possession of and, with or without advertisement, sell at public or private sale all or any part of the property on which the Government has a lien under this contract and, after deducting any expenses incident to the sale, apply the net proceeds of the sale to

reduce the unliquidated balance of advance payments or other Government claims against the Contractor.

(3) The Government may take any of the actions described in paragraphs(k)(1) and (2) of this clause it considers appropriate at its discretion and without limiting any other rights of the Government.

(l) Prohibition against assignment. Notwithstanding any other terms of this contract, the Contractor shall not assign this contract, any interest therein, or any claim under the contract to any party.

(m) Information and access to records. The Contractor shall furnish to the administering office (1) monthly or at other intervals as required, signed or certified balance sheets and profit and loss statements together with a report on the operation of the special account in the form prescribed by the administering office; and (2) if requested, other information concerning the operation of the Contractor's business. The Contractor shall provide the authorized Government representatives proper facilities for inspection of the Contractor's books, records, and accounts.

(n) Other security. The terms of this contract are considered to provide adequate security to the Government for advance payments; however, if the administering office considers the security inadequate, the Contractor shall furnish additional security satisfactory to the administering office, to the extent that the security is available.

(o) Representations. The Contractor represents the following:

(1) The balance sheet, the profit and loss statement, and any other supporting financial statements furnished to the administering office fairly reflect the financial condition of the Contractor at the date shown or the period covered, and there has been no subsequent materially adverse change in the financial condition of the Contractor.

(2) No litigation or proceedings are presently pending or threatened against the Contractor, except as shown in the financial statements.

(3) The Contractor has disclosed all contingent liabilities, except for liability resulting from the renegotiation of defense production contracts, in the financial statements furnished to the administering office.

(4) None of the terms in this clause conflict with the authority under which the Contractor is doing business or with the provision of any existing indenture or agreement of the Contractor.

(5) The Contractor has the power to enter into this contract and accept advance payments, and has taken all necessary action to authorize the acceptance under the terms of this contract.

(6) The assets of the Contractor are not subject to any lien or encumbrance of any character except for current taxes not delinquent, and except as shown in the financial statements furnished by the Contractor. There is no current assignment of claims under any contract affected by these advance payment provisions.

(7) All information furnished by the Contractor to the administering office in connection with each request for advance payments is true and correct.
(8) These representations shall be continuing and shall be considered to have been repeated by the submission of each invoice for advance payments.

(p) Covenants. To the extent the Government considers it necessary while any advance payments made under this contract remain outstanding, the Contractor, without the prior written consent of the administering office, shall not-
(1) Mortgage, pledge, or otherwise encumber or allow to be encumbered, any of the assets of the Contractor now owned or subsequently acquired, or permit any preexisting mortgages, liens, or other encumbrances to remain on or attach to any assets of the Contractor which are allocated to performing this contract and with respect to which the Government has a lien under this contract;
(2) Sell, assign, transfer, or otherwise dispose of accounts receivable, notes, or claims for money due or to become due;
(3) Declare or pay any dividends, except dividends payable in stock of the corporation, or make any other distribution on account of any shares of its capital stock, or purchase, redeem, or otherwise acquire for value any of its stock, except as required by sinking fund or redemption arrangements reported to the administering office incident to the establishment of these advance payment provisions;
(4) Sell, convey, or lease all or a substantial part of its assets;
(5) Acquire for value the stock or other securities of any corporation, municipality, or governmental authority, except direct obligations of the United States;
(6) Make any advance or loan or incur any liability as guarantor, surety, or accommodation endorser for any party;
(7) Permit a writ of attachment or any similar process to be issued against its property without getting a release or bonding the property within 30 days after the entry of the writ of attachment or other process;
(8) Pay any remuneration in any form to its directors, officers, or key employees higher than rates provided in existing agreements of which notice has been given to the administering office; accrue excess remuneration without first obtaining an agreement subordinating it to all claims of the Government; or charge direct labor for any person at a rate of compensation over *Executive Level II Rate* a year;
(9) Change substantially the management, ownership, or control of the corporation;
(10) Merge or consolidate with any other firm or corporation, change the type of business, or engage in any transaction outside the ordinary course of the Contractor's business as presently conducted;
(11) Deposit any of its funds except in a bank or trust company insured by the Federal Deposit Insurance Corporation or a credit union insured by the National Credit Union Administration;
(12) Create or incur indebtedness for advances, other than advances to be made under the terms of this contract, or for borrowings;
(13) Make or covenant for capital expenditures exceeding [redacted] in total;

(14) Permit its net current assets, computed in accordance with generally accepted accounting principles, to become less than [redacted] or

(15) Make any payments on account of the obligations listed below, except in the manner and to the extent provided in this contract:

(End of clause)

15. FAR Clause **52.232-19, Availability of Funds for the Next Fiscal Year** (April 1984).

Funds are not presently available for performance under this contract beyond _____ . The Government's obligation for performance of this contract beyond that date is contingent upon the availability of appropriated funds from which payment for contract purposes can be made. No legal liability on the part of the Government for any payment may arise for performance under this contract beyond _____ , until funds are made available to the Contracting Officer for performance and until the Contractor receives notice of availability, to be confirmed in writing by the Contracting Officer.

16. FAR Clause **52.244-2, Subcontracts** (June 2020), with **Alternate I** (June 2007)

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

"Approved purchasing system" means a Contractor's purchasing system that has been reviewed and approved in accordance with Part 44 of the Federal Acquisition Regulation (FAR)

"Consent to subcontract" means the Contracting Officer's written consent for the Contractor to enter into a particular subcontract.

"Subcontract" means any contract, as defined in FAR Subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(b) When this clause is included in a fixed-price type contract, consent to subcontract is required only on unpriced contract actions (including unpriced modifications or unpriced delivery orders), and only if required in accordance with paragraph (c) or (d) of this clause.

(c) If the Contractor does not have an approved purchasing system, consent to subcontract is required for any subcontract that-

(1) Is of the cost-reimbursement, time-and-materials, or labor-hour type; or

(2) Is fixed-price and exceeds—

(i) For a contract awarded by the Department of Defense, the Coast Guard, or the National Aeronautics and Space Administration, the greater of the simplified acquisition threshold or 5 percent of the total estimated cost of the contract; or

(ii) For a contract awarded by a civilian agency other than the Coast Guard and the National Aeronautics and Space Administration, either the simplified acquisition threshold or 5 percent of the total estimated cost of the contract.

(d) If the Contractor has an approved purchasing system, the Contractor nevertheless shall obtain the Contracting Officer's written consent before placing the following subcontracts:

Foreign and Legal Services

(e)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (b), (c), or (d) of this clause, including the following information:

(i) A description of the supplies or services to be subcontracted.

(ii) Identification of the type of subcontract to be used.

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

(v) The subcontractor's current, complete, and accurate certified cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract.

(vii) A negotiation memorandum reflecting -

(A) The principal elements of the subcontract price negotiations;

(B) The most significant considerations controlling establishment of initial or revised prices;

(C) The reason certified cost or pricing data were or were not required;

(D) The extent, if any, to which the Contractor did not rely on the subcontractor's certified cost or pricing data in determining the price objective and in negotiating the final price;

(E) The extent to which it was recognized in the negotiation that the subcontractor's certified cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F) The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(2) If the Contractor has an approved purchasing system and consent is not required under paragraph (c), or (d) of this clause, the Contractor nevertheless shall notify the Contracting Officer reasonably in advance of entering into any (i)cost-plus-fixed-fee subcontract, or (ii)fixed-price subcontract that exceeds either the simplified acquisition threshold or 5 percent of the total estimated cost of this contract. The notification shall include the information required by paragraphs(e)(1)(i) through (e)(1)(iv) of this clause.

(f) Unless the consent or approval specifically provides otherwise, neither consent by the Contracting Officer to any subcontract nor approval of the Contractor's purchasing system shall constitute a determination -

(1) Of the acceptability of any subcontract terms or conditions;
(2) Of the allowability of any cost under this contract; or
(3) To relieve the Contractor of any responsibility for performing this contract.

(g) No subcontract or modification thereof placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.404-4(c)(4)(i).

(h) The Contractor shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Contractor by any subcontractor or vendor that, in the opinion of the Contractor, may result in litigation related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(i) The Government reserves the right to review the Contractor's purchasing system as set forth in FAR Subpart 44.3.

(j) Paragraphs (c) and (e) of this clause do not apply to the following subcontracts, which were evaluated during negotiations:

(End of Clause)

B. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR **352.227-14 Rights in Data-Exceptional Circumstances** (September 2014)

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

Computer database or *database* means a collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

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

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

(ii) Does not include computer databases or computer software documentation.

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

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

Form, fit, and function data means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For computer software it means data identifying source, functional characteristics, and performance requirements but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

Limited rights means the rights of the Government in limited rights data as set forth in the Limited Rights Notice in Alternate II paragraph (g)(3) if included in

this clause. "Limited rights data" means data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.

Restricted computer software means computer software developed at private expense and that is a trade secret, is commercial or financial and confidential or privileged, or is copyrighted computer software, including minor modifications of the computer software.

Restricted rights, as used in this clause, means the rights of the Government in restricted computer software, as set forth in a Restricted Rights Notice of Alternate III paragraph (g)(4) if included in this clause, or as otherwise may be provided in a collateral agreement incorporated in and made part of this contract, including minor modifications of such computer software.

Technical data means recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including computer databases and computer software documentation). This term does not include computer software or financial, administrative, cost or pricing, or management data or other information incidental to contract administration. The term includes recorded information of a scientific or technical nature that is included in computer databases (See 41 U.S.C. 403 (8)).

Unlimited rights means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

(b) *Allocation of rights.* (1) Except as provided in paragraph (c) of this clause, the Government shall have unlimited rights in-

(i) Data first produced in the performance of this contract;

(ii) Form, fit, and function data delivered under this contract;

(iii) Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this contract; and

(iv) All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph (g) of this clause.

(2) The Contractor shall have the right to-

(i) Assert copyright in data first produced in the performance of this contract to the extent provided in paragraph (c)(1) of this clause;

(ii) Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, unless provided otherwise in paragraph (d) of this clause;

(iii) Substantiate the use of, add, or correct limited rights, restricted rights, or copyright notices and to take other appropriate action, in accordance with paragraphs (e) and (f) of this clause; and

(iv) Protect from unauthorized disclosure and use those data that are limited rights data or restricted computer software to the extent provided in paragraph (g) of this clause.

(c) *Copyright.* (1) *Data first produced in the performance of this contract.* (i) Unless provided otherwise in paragraph (d) of this clause, the Contractor may, without prior approval of the Contracting Officer, assert copyright in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings, or similar works. The prior, express written permission of the Contracting Officer is required to assert copyright in all other data first produced in the performance of this contract.

(ii) When authorized to assert copyright to the data, the Contractor shall affix the applicable copyright notices of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number).

(iii) For data other than computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government. For computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and

display publicly (but not to distribute copies to the public) by or on behalf of the Government.

(2) Data not first produced in the performance of this contract. The Contractor shall not, without the prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract unless the Contractor-

(i) Identifies the data; and

(ii) Grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause or, if such data are restricted computer software, the Government shall acquire a copyright license as set forth in paragraph (g)(4) of this clause (if included in this contract) or as otherwise provided in a collateral agreement incorporated in or made part of this contract.

(3) *Removal of copyright notices.* The Government will not remove any authorized copyright notices placed on data pursuant to this paragraph (c), and will include such notices on all reproductions of the data.

(d) Release, publication, and use of data. The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except-

(1) As prohibited by Federal law or regulation (*e.g.,* export control or national security laws or regulations);

(2) As expressly set forth in this contract; or

(3) If the Contractor receives or is given access to data necessary for the performance of this contract that contain restrictive markings, the Contractor shall treat the data in accordance with such markings unless specifically authorized otherwise in writing by the Contracting Officer or in the following paragraphs.

(4) In addition to any other provisions, set forth in this contract, the Contractor shall ensure that information concerning possible inventions made under this contract is not prematurely published thereby adversely affecting the ability to obtain patent protection on such inventions. Accordingly, the Contractor will provide the Contracting Officer a copy of any publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure. Upon the Contracting Officer's request the Contractor

agrees to delay the public disclosure of such data or publication of a specified paper for a reasonable time specified by the Contracting Officer, not to exceed 6 months, to allow for the filing of domestic and international patent applications in accordance with Clause 352.227-11, Patent Rights-Exceptional Circumstances (abbreviated month and year of Final Rule publication).

(5) *Data on Material(s).* The Contractor agrees that in accordance with paragraph (d)(2), proprietary data on Material(s) provided to the Contractor under or through this contract shall be used only for the purpose for which they were provided, including screening, evaluation or optimization and for no other purpose.

(6) *Confidentiality.* (i) The Contractor shall take all reasonable precautions to maintain Confidential Information as confidential, but no less than the steps Contractor takes to secure its own confidential information.

(ii) Contractor shall maintain Confidential Information as confidential unless specifically authorized otherwise in writing by the Contracting Officer. Confidential Information includes/does not include [Government may define confidential information here.]

(e) *Unauthorized marking of data.* (1) Notwithstanding any other provisions of this contract concerning inspection or acceptance, if any data delivered under this contract are marked with the notices specified in paragraph (g)(3) or (4) of this clause (if those alternate paragraphs are included in this clause), and use of the notices is not authorized by this clause, or if the data bears any other restrictive or limiting markings not authorized by this contract, the Contracting Officer may cancel or ignore the markings. However, pursuant to 41 U.S.C. 253 d, the following procedures shall apply prior to canceling or ignoring the markings.

(i) The Contracting Officer will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings;

(ii) If the Contractor fails to respond or fails to provide written justification to substantiate the propriety of the markings within the 60-day period (or a longer time approved in writing by the Contracting Officer for good cause shown), the Government shall have the right to cancel or ignore the markings at any time after said period and the data will no longer be made subject to any disclosure prohibitions.

(iii) If the Contractor provides written justification to substantiate the propriety of the markings within the period set in paragraph (e)(1)(i) of this clause, the

Contracting Officer will consider such written justification and determine whether or not the markings are to be cancelled or ignored. If the Contracting Officer determines that the markings are authorized, the Contractor will be so notified in writing. If the Contracting Officer determines, with concurrence of the head of the contracting activity, that the markings are not authorized, the Contracting Officer will furnish the Contractor a written determination, which determination will become the final Agency decision regarding the appropriateness of the markings unless the Contractor files suit in a court of competent jurisdiction within 90 days of receipt of the Contracting Officer's decision. The Government will continue to abide by the markings under this paragraph(e)(1)(iii) until final resolution of the matter either by the Contracting Officer's determination becoming final (in which instance the Government will thereafter have the right to cancel or ignore the markings at any time and the data will no longer be made subject to any disclosure prohibitions), or by final disposition of the matter by court decision if suit is filed.

(2) The time limits in the procedures set forth in paragraph (e)(1) of this clause may be modified in accordance with Agency regulations implementing the Freedom of Information Act (5 U.S.C. 552) if necessary to respond to a request there under.

(3) Except to the extent the Government's action occurs as the result of final disposition of the matter by a court of competent jurisdiction, the Contractor is not precluded by this paragraph

(e) from bringing a claim, in accordance with the Disputes clause of this contract, that may arise as the result of the Government removing or ignoring authorized markings on data delivered under this contract.

(f) *Omitted or incorrect markings.* (1) Data delivered to the Government without any restrictive markings shall be deemed to have been furnished with unlimited rights. The Government is not liable for the disclosure, use, or reproduction of such data.

(2) If the unmarked data has not been disclosed without restriction outside the Government, the Contractor may request, within 6 months (or a longer time approved by the Contracting Officer in writing for good cause shown) after delivery of the data, permission to have authorized notices placed on the data at the Contractor's expense. The Contracting Officer may agree to do so if the Contractor-

(i) Identifies the data to which the omitted notice is to be applied;

(ii) Demonstrates that the omission of the notice was inadvertent;

(iii) Establishes that the proposed notice is authorized; and

(iv) Acknowledges that the Government has no liability for the disclosure, use, or reproduction of any data made prior to the addition of the notice or resulting from the omission of the notice.

(3) If data has been marked with an incorrect notice, the Contracting Officer may-

(i) Permit correction of the notice at the Contractor's expense if the Contractor identifies the data and demonstrates that the correct notice is authorized; or

(ii) Correct any incorrect notices.

(g) *Protection of limited rights data and restricted computer software.*

(1) The Contractor may withhold from delivery qualifying limited rights data or restricted computer software that are not data identified in paragraphs (b)(1)(i) through (iii) of this clause. As a condition to this withholding, the Contractor shall-

(i) Identify the data being withheld; and

(ii) Furnish form, fit, and function data instead.

(2) Limited rights data that are formatted as a computer database for delivery to the Government shall be treated as limited rights data and not restricted computer software.

(3) [Reserved]

(h) *Subcontracting.* The Contractor shall obtain from its subcontractors all data and rights therein necessary to fulfill the Contractor's obligations to the Government under this contract. If a subcontractor refuses to accept terms affording the Government those rights, the Contractor shall promptly notify the Contracting Officer of the refusal and shall not proceed with the subcontract award without authorization in writing from the Contracting Officer.

(i) Relationship to patents or other rights. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government.

(End of clause)

Alternate I (SEPT 2014). As prescribed in *327.409,* substitute the following definition for "limited rights data" in paragraph (a) of the basic clause:

Limited rights data means data, other than computer software, developed at private expense that embody trade secrets or are commercial or financial and confidential or privileged.

Alternate II (SEPT 2014). As prescribed in *327.409,* insert the following paragraph (g)(3) in the basic clause:

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (SEPT 2014)

(a) These data are submitted with limited rights under Government Contract No. 75N91019D00024 (and subcontract _TBD_, if appropriate). These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure: [Agencies may list additional purposes or if none, so state.]

(b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice)

Alternate III (SEPT 2014). As prescribed in *327.409,* insert the following paragraph (g)(4) in the basic clause: (g)(4)(i) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of restricted computer software, or the Contracting Officer may require by written request

the delivery of restricted computer software that has been withheld or would otherwise be entitled to be withheld. If delivery of that computer software is required, the Contractor shall affix the following "Restricted Rights Notice" to the computer software and the Government will treat the computer software, subject to paragraphs (e) and (f) of this clause, in accordance with the notice:

Restricted Rights Notice (SEPT 2014)

(a) This computer software is submitted with restricted rights under Government Contract No. 75N91019D00024 (and subcontract _TBD_, if appropriate). It may not be used, reproduced, or disclosed by the Government except as provided in paragraph (b) of this notice or as otherwise expressly stated in the contract.

(b) This computer software may be-

(1) Used or copied for use with the computer(s) for which it was acquired, including use at any Government installation to which the computer(s) may be transferred;

(2) Used or copied for use with a backup computer if any computer for which it was acquired is inoperative;

(3) Reproduced for safekeeping (archives) or backup purposes;

(4) Modified, adapted, or combined with other computer software, provided that the modified, adapted, or combined portions of the derivative software incorporating any of the delivered, restricted computer software shall be subject to the same restricted rights;

(5) Disclosed to and reproduced for use by support service Contractors or their subcontractors in accordance with paragraphs (b)(1) through (4) of this notice; and

(6) Used or copied for use with a replacement computer.

(c) Notwithstanding the foregoing, if this computer software is copyrighted computer software, it is licensed to the Government with the minimum rights set forth in paragraph (b) of this notice.

(d) Any other rights or limitations regarding the use, duplication, or disclosure of this computer software are to be expressly stated in, or incorporated in, the contract.

(e) This notice shall be marked on any reproduction of this computer software, in whole or in part.

(End of notice)

(ii) Where it is impractical to include the Restricted Rights Notice on restricted computer software, the following short-form notice may be used instead:

Restricted Rights Notice Short Form (SEPT 2014)

Use, reproduction, or disclosure is subject to restrictions set forth in Contract No. 75N91019D00024 (and subcontract, if appropriate) with _TBD_ (name of Contractor and subcontractor).

(End of notice)

(iii) If restricted computer software is delivered with the copyright notice of 17 U.S.C. 401 , it will be presumed to be licensed to the Government without disclosure prohibitions, with the minimum rights set forth in paragraph (b) of this clause.

Alternate IV (SEPT 2014). As prescribed in *327.409,* substitute the following paragraph (c)(1) for paragraph (c)(1) of the basic clause:

(c) *Copyright* -(1) *Data first produced in the performance of the contract.* Except as otherwise specifically provided in this contract, the Contractor may assert copyright in any data first produced in the performance of this contract. When asserting copyright, the Contractor shall affix the applicable copyright notice of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number), to the data when such data are delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. For data other than computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. For computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public), by or on behalf of the Government.

Alternate V (SEPT 2014). As prescribed in *327.409,* add the following paragraph (j) to the basic clause:

(j) The Contractor agrees, except as may be otherwise specified in this contract for specific data deliverables listed as not subject to this paragraph, that the Contracting Officer may, up to 3 years after acceptance of all deliverables under this contract, inspect at the Contractor's facility any data withheld pursuant to paragraph (g)(1) of this clause, for purposes of verifying the Contractor's assertion of limited rights or restricted rights status of the data or for evaluating work performance. When the Contractor whose data are to be inspected demonstrates to the Contracting Officer that there would be a possible conflict of interest if a particular representative made the inspection, the Contracting Officer shall designate an alternate inspector.

2. HHSAR Clause **352.237-74, Non-Discrimination in Service Delivery** (December 2015).

It is the policy of the Department of Health and Human Services that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental). By acceptance of this contract, the contractor agrees to comply with this policy in supporting the program and in performing the services called for under this contract. The contractor shall include this clause in all subcontracts awarded under this contract for supporting or performing the specified program and services. Accordingly, the contractor shall ensure that each of its employees, and any sub-contractor staff, is made aware of, understands, and complies with this policy.

(End of Clause)

ARTICLE I.5 SERVICE CONTRACT LABOR STANDARDS AND LABOR LAWS (APPLICABLE AT THE SUBCONTRACT LEVEL ONLY)

The following clauses are hereby incorporated and made a part of this contract. All clauses incorporated by reference have the same force and effect as if they were given full text. Upon request, the Contracting Officer will make their full text available.

A. FAR Clause **52.222-6, Construction Wage Rate Requirements** (Aug 2018)

B. FAR Clause **52.222-7, Withholding of Funds** (May 2014)

C. FAR Clause **52.222-8, Payrolls and Basic Records** (Aug 2018)

D. FAR Clause **52.222-9, Apprentices and Trainees** (July 2005)

E. FAR Clause **52.222-10, Compliance with Copeland Act Requirements** (Feb 1988)

F. FAR Clause **52.222-11, Subcontracts (Labor Standards)** (May 2014)

G. FAR Clause **52.222-12, Contract Termination-Debarment** (May 2014)

H. FAR Clause **52.222-13, Compliance with Construction Wage Rate Requirements and Related Regulations** (May 2014)

I. FAR Clause **52.222-14, Disputes Concerning Labor Standards** (Feb 1988)

J. FAR Clause **52.222-15, Certification of Eligibility** (May 2014)

K. FAR Clause **52.222-17 Nondisplacement of Qualified Workers** (May 2014).

L. FAR Clause **52.222-41, Service Contract Labor Standards** (May 2014).

M. FAR Clause **52.222-42, Statement of Equivalent Rates For Federal Hires** (Aug 2018)

In compliance with the Contract Labor Standards statute and the regulations of the Secretary of Labor (29 CFR Part 4), this clause identifies the classes of service employees expected to be employed under the contract and states the wages and fringe benefits payable to each if they were employed by the contracting agency subject to the provisions of 5 U.S.C. 5341 or 5332.

N. FAR Clause **52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment** (Multiple Year And Option Contracts) (Aug 2018).

O. FAR Clause **52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment** (May 2014).

P. FAR Clause **52.222-49, Service Contract Labor Standards--Place Of Performance Unknown** (May 2014)

a. "(a) ....., wage determinations have been requested for the following: Frederick County, Maryland. The Contracting Officer will request wage determinations for additional places or areas of performance if asked to do so in writing by June 24, 2029....."

Q. FAR **52.222-55, Minimum Wages Under Executive Order 13658** (December 2015)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this Contract:

Attachment No.	Title	Location
Attachment 1:	Provisional Rate Agreement and Labor Rate Ranges, Dated 05/27/2020, 63 pages.	Attached
Attachment 2:	Licenses and Permits, Dated 06/26/2019, 2 pages.	Attached
Attachment 3:	FAR Clause Deviations, April 2017, 18 pages.	Attached
Attachment 4:	Statement of Work, Dated 06/16/2020, 19 pages.	Attached
Attachment 5:	Cumulative Inclusion Enrollment Report	Cumulative Inclusion Enrollment Report, PHS 398/2590, (Rev. 08/12), 1 page. Located at: http://grants.nih.gov/grants/funding/phs398/CumulativeInclusionEnrollmentReport.pdf
Attachment 6:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc4_508.pdf
Attachment 7:	Invoice Instructions for NIH Fixed Price Contracts NIH(RC)-2	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc2_508.pdf
Attachment 8:	Report of Government Owned, Contractor Held Property, Dated 10/2014, 1 page	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Govt-Owned-Prop.pdf
Attachment 9:	Government Property Schedule II-A, Dated 03/15/2019, 3,400 pages.	Attached
Attachment 10:	Sale of Research Substances and/or Living Organisms:	Attached

	Monthly Summary of Sales, 03/28/2018, 1 Page.	
Attachment 11:	Sale of Research Substances and/or Living Organisms: Sample Recipient Invoice, 03/07/2018, 1 Page.	Attached
Attachment 12:	Sale of Research Substances and/or Living Organisms: NIH Pay.gov User Guide, March 2018, 16 Pages.	Attached
Attachment 13:	Small Business Subcontracting Plan, Dated 06/26/2019, 16 pages.	Attached
Attachment 14:	Commitment to Protect Non-Public Information Contractor Agreement	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf
Attachment 15:	Privacy Act System of Records	The Privacy Act System of Records applicable to this project are Numbers 09-25-0005, 09-25-0007, 09-25-0054, 09-25-0087, 09-25-0099, 09-25-0105, 09-25-0115, 09-25-0118, 09-25-0166, 09-25-0168, 09-25-0169, 09-25-0200, 09-25-0216, 09-25-0223, 09-90-0001, 09-90-0005, 09-90-0024, and 09-90-0777. These documents are also available at: https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/read02systems.htm
Attachment 16:	Conference Expense Offset Worksheets	Contractor Pre-Conference Expense Offset Worksheet, 1 page. Located at: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Pre-Conf-worksheet.pdf Post Conference Expense Offset Worksheet, 2 pages. Located at: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Post-Conf-worksheet.pdf
Attachment 17:	Performance Guarantee, Dated 06/24/2019, 2 pages.	Attached
Attachment 18:	Safety and Health, HHSAR Clause 352.223-70	https://oamp.od.nih.gov/sites/default/files/DGS/FORMS/hhsar_352.223-70_safety_and_health_508.pdf
Attachment 19:	Research Patient Care Costs, NIH(RC)-11, 4/1/84, 1 page.	Reserved

Attachment 20:	FAR Clause 52.222-6, Construction Wage Rate Requirements (Aug 2018), Davis-Bacon Act WRD#:MD20190055, Frederick County, MD	https://beta.sam.gov/wage-determination/MD20190055/0?index=wd&keywords=Maryland&sort=-relevance&date_filter_index=0&date_rad_selection=date&wdType=dbra&page=1
Attachment 21:	FAR Clause 52.222-41, Service Contract Labor Standards (Aug 2018), Service Contract Act WD#: 2015-4270, Frederick County, MD	https://beta.sam.gov/wage-determination/2015-4270/9?index=wd&keywords=Maryland&sort=-relevance&date_filter_index=0&date_rad_selection=date&wdType=sca&page=2
Attachment 22:	FAR Clause 52.222-42, Statement of Equivalent Rates For Federal Hires (May 2014)	White Collar: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/18Tables/html/DCB_h.aspx Blue Collar: https://www.cpms.osd.mil/Content/AF%20Schedules/survey-sch/027/027R-29Dec2017.html
Attachment 23:	Listing of Building Responsibility, Dated 06/26/2019, 5 pages.	Attached
Attachment 24:	Electronic Invoicing Instructions for NIH Contractors/Vendors	Attached

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

1. FAR Clause 52.204-19 **Incorporation by Reference of Representations and Certifications** (December 2014).

   The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract. (End of clause).

2. Human Subjects Assurance Identification Number: FWA00021921.

3. Animal Welfare Assurance Number: D16-00605 (A4159-01).

END of the SCHEDULE