PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

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Parent topic: SUBCHAPTER H—CLAUSES AND FORMS

Subpart 352.1—Instructions for Using Provisions and Clauses

352.100 Scope of subpart.

This subpart provides guidance for applying the Department of Health and Human Services provisions and clauses in solicitations, contracts, and orders.

352.101-70 Application of provisions and clauses.

(a) If a clause is included in the master instrument (e.g., in an indefinite delivery/indefinite quantity contract or a blanket purchase agreement), it is not necessary to also include the clause in a task order or delivery order thereunder.

(b) When a dollar amount or dollar threshold is specified (e.g., $25 million or simplified acquisition threshold), the dollar amount of the award (contract or order) includes any options thereunder.

Subpart 352.2—Texts of Provisions and Clauses

352.203-70 Anti-Lobbying.

As prescribed in HHSAR 303.808-70, the Contracting Officer shall insert the following clause:

Anti-Lobbying (DEC 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for:

(a) Publicity or propaganda purposes;

(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic

communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

(c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

(d) The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

(End of clause)

352.204-70 Prevention and Public Health Fund—Reporting Requirements.

As prescribed in HHSAR 304.7201, insert the following clause:

Prevention and Public Health Fund—Reporting Requirements (DEC 2015)

(a) Pursuant to public law this contract requires the contractor to provide products or services or both that are funded from the Prevention and Public Health Fund (PPHF), Public Law 111-148, sec. 4002. Section 220(b)(5) requires each contractor to report on its use of these funds under this contract. These reports will be made available to the public.

(b) Semi-annual reports from the Contractor for all work funded, in whole or in part, by the PPHF, are due no later than 20 days following the end of each 6-month period. The 6-month reporting periods are January through June and July through December. The first report is due no later than 20 days after the end of the 6-month period following contract award. Subsequent reports are due no later than 20 days after the end of each reporting period. If applicable, the Contractor shall submit its final report for the remainder of the contract period no later than 20 days after the end of the reporting period in which the contract ended.

(c) The Contractor shall provide the following information in an electronic and Section 508 compliant format to the Contracting Officer.

(1) The Government contract and order number, as applicable.

(2) The amount of PPHF funds invoiced by the contractor for the reporting period and the cumulative amount invoiced for the contract or order.

(3) A list of all significant services performed or supplies delivered, including construction, for which the contractor invoiced in the reporting period.

(4) Program or project title, if any.

(5) The Contractor shall report any subcontract funded in whole or in part with PPHF funding, that is valued at $25,000 or more. The Contractor shall advise the subcontractor that the information will be made available to the public. The Contractor shall report:

(i) Name and address of the subcontractor.

(ii) Amount of the subcontract award.

(iii) Date of the subcontract award.

(iv) A description of the products or services (including construction) being provided under the subcontract.

(End of clause)

352.208-70 Printing and Duplication.

As prescribed in HHSAR 308.803, the Contracting Officer shall insert the following clause:

Printing and Duplication (DEC 2015)

(a) Unless otherwise specified in this contract, no printing by the Contractor or any subcontractor is authorized under this contract. All printing required must be performed by the Government Printing Office except as authorized by the Contracting Officer. The Contractor shall submit camera-ready copies to the Contracting Officer's Representative (COR). The terms “printing” and “duplicating/copying” are defined in the Government Printing and Binding Regulations of the Joint Committee on Printing.

(b) If necessary for performance of the contract, the Contractor may duplicate or copy less than 5,000 production units of only one page, or less than 25,000 production units in aggregate of multiple pages for the use of a department or agency. A production unit is defined as one sheet, size 8.5 x 11 inches, one side only, and one color. The pages may not exceed a maximum image size of 10 3/4 by 14 1/4 inches. This page limit applies to each printing requirement and not for all printing requirements under the entire contract.

(c) Approval for all printing, as well as duplicating/copying in excess of the stated limits, shall be obtained from the COR who will consult with the designated publishing services office and provide direction to the contractor. The cost of any unauthorized printing or duplicating/copying under this contract will be considered an unallowable cost for which the Contractor will not be reimbursed.

352.211-1 Public Accommodations and Commercial Facilities.

As prescribed in HHSAR 311.7102, the Contracting Officer shall insert the following clause:

Public Accommodations and Commercial Facilities (DEC 2015)

The Contractor agrees as follows:

(a) Except for ad hoc meetings necessary or incidental to contract performance, the Contractor shall develop a plan to assure that any event held pursuant to this contract will meet or exceed the minimum accessibility standards set forth in 28 CFR part 36—Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities. The Contractor shall submit the plan to the Contracting Officer and must receive approval prior to the event. The Contractor may submit a consolidated or master plan for contracts requiring numerous events in lieu of separate plans.

(b) The Contractor shall manage the contract in accordance with the standards set forth in 28 CFR part 36.

(End of clause)

352.211-2 Conference Sponsorship Requests and Conference Materials Disclaimer.

As prescribed in HHSAR 311.7202, the Contracting Officer shall insert the following clause:

Conference Sponsorship Request and Conference Materials Disclaimer (DEC 2015)

(a) If HHS is not the sole provider of funding under this contract, then, prior to the Contractor claiming HHS conference sponsorship, the Contractor shall submit a written request (including rationale) to the Contracting Officer for permission to claim such HHS sponsorship.

(b) Whether or not HHS is the conference sponsor, the Contractor shall include the following statement on conference materials, including promotional materials, agendas, and Web sites:

“This conference was funded, in whole or in part, through a contract (insert contract number) with the Department of Health and Human Services (HHS) (insert name of OPDIV or STAFFDIV). The views expressed in written conference materials and by speakers and moderators at this conference, do not necessarily reflect the official policies of HHS, nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.”

(c) Unless authorized in writing by the Contracting Officer, the Contractor shall not display the HHS logo on any conference materials.

(End of clause)

352.211-3 Paperwork Reduction Act.

As prescribed in HHSAR 311.7301, the Contracting Officer shall insert the following clause:

Paperwork Reduction Act (DEC 2015)

(a) This contract involves a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties; therefore, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single time) may be used without the

Office of Management and Budget (OMB) first providing clearance. Contractors and the Contracting Officer's Representative shall be guided by the provisions of 5 CFR part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

(b) The Contractor shall not expend any funds or begin any data collection until the Contracting Officer provides the Contractor with written notification authorizing the expenditure of funds and the collection of data. The Contractor shall allow at least 120 days for OMB clearance. The Contracting Officer will consider excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Contractor in accordance with the Excusable Delays or Default clause of this contract.

(End of clause)

352.215-70 Late Proposals and Revisions.

As prescribed in HHSAR 315.208, the Contracting Officer shall insert the following provision:

Late Proposals and Revisions (DEC 2015) Deviation

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, the Government may consider a proposal received after the date specified for receipt if it appears to offer significant cost or technical advantage to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

352.216-70 Additional Cost Principles for Hospitals (Profit and Non-Profit).

As prescribed in HHSAR 316.307(a)(2), the Contracting Officer shall insert the following clause:

Additional Cost Principles for Hospitals (Profit or Non-Profit) (DEC 2015)

(a) *Bid and proposal (B&P) costs.*

(1) B&P costs are the immediate costs of preparing bids, proposals, and applications for potential Federal and non-Federal contracts, grants, and agreements, including the development of scientific, cost, and other data needed to support the bids, proposals, and applications.

(2) B&P costs of the current accounting period are allowable as indirect costs.

(3) B&P costs of past accounting periods are unallowable in the current period. However, if the organization's established practice is to treat these costs by some other method, they may be accepted if they are found to be reasonable and equitable.

(4) B&P costs do not include independent research and development (IR&D) costs covered by the following paragraph, or pre-award costs covered by paragraph 36 of Attachment B to OMB Circular A-122.

(b) *IR&D costs.*

(1) IR&D is research and development conducted by an organization which is not sponsored by Federal or non-Federal contracts, grants, or other agreements.

(2) IR&D shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development.

(3) The cost of IR&D, including its proportionate share of indirect costs, is unallowable.

(End of clause)

352.219-70 Mentor-Protégé Program.

As prescribed in HHSAR 319.270-1(a), the Contracting Officer shall insert the following provision:

Mentor-Protégé Program (DEC 2015)

(a) Large business prime contractors serving as mentors in the HHS Mentor-Protégé Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU)-approved mentor-protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at *www.esrs.gov*. The mentor firm and protégé firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a $10,000 subcontract awarded to a protégé firm and provision of $5,000 of developmental assistance as $15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

(b) The program consists of—

(1) *Mentor firms*—large businesses that:

(i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and

(ii) Have a Mentor-Protégé agreement approved by HHS' OSDBU;

(2) *Protégé firms*—firms that:

(i) Seek developmental assistance;

(ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and

(iii) Have a Mentor-Protégé agreement approved by HHS' OSDBU; and

(3) *Mentor-Protégé agreements*—joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

352.219-71 Mentor-Protégé Program Reporting Requirements.

As prescribed in HHSAR 319.270-1(b), the Contracting Officer shall insert the following clause:

Mentor-Protégé Program Reporting Requirements (January 2010)

The Contractor shall comply with all reporting requirements specified in its Mentor-Protégé agreement approved by HHS' OSDBU.

(End of clause)

352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations.

As prescribed in HHSAR 322.810(h), the Contracting Officer shall insert the following clause:

Contractor Cooperation in Equal Employment Opportunity Investigations (DEC 2015)

(a) In addition to complying with the clause at FAR 52.222-26, Equal Opportunity, the Contractor shall, in good faith, cooperate with the Department of Health and Human Services (Agency) in investigations of Equal Employment Opportunity (EEO) complaints processed pursuant to 29 CFR part 1614. For purposes of this clause, the following definitions apply:

(1) *Complaint* means a formal or informal complaint that has been lodged with Agency management, Agency EEO officials, the Equal Employment Opportunity Commission (EEOC), or a court of competent jurisdiction.

(2) *Contractor employee* means all current Contractor employees who work or worked under this contract. The term also includes current employees of subcontractors who work or worked under this contract. In the case of Contractor and subcontractor employees, who worked under this contract, but who are no longer employed by the Contractor or subcontractor, or who have been assigned to another entity within the Contractor's or subcontractor's organization, the Contractor shall provide the Agency with that employee's last known mailing address, email address, and telephone number, if that employee has been identified as a witness in an EEO complaint or investigation.

(3) *Good faith cooperation* cited in paragraph (a) includes, but is not limited to, making Contractor employees available for:

(i) Formal and informal interviews by EEO counselors or other Agency officials processing EEO complaints;

(ii) Formal or informal interviews by EEO investigators charged with investigating complaints of unlawful discrimination filed by Federal employees;

(iii) Reviewing and signing appropriate affidavits or declarations summarizing statements provided by such Contractor employees during the course of EEO investigations;

(iv) Producing documents requested by EEO counselors, EEO investigators, Agency employees, or the EEOC in connection with a pending EEO complaint; and

(v) Preparing for and providing testimony in depositions or in hearings before the MSPB, EEOC and U.S. District Court.

(b) The Contractor shall include the provisions of this clause in all subcontract solicitations and subcontracts awarded at any tier under this contract.

(c) Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause may be grounds for the Contracting Officer to terminate this contract for default.

(End of clause)

352.223-70 Safety and Health.

As prescribed in HHSAR 323.7002, the Contracting Officer shall insert the following clause:

Safety and Health (DEC 2015)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.

(1) In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:

(i) 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR part 1910. These regulations are available at *https://www.osha.gov/*.

(ii) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 *et seq*.). The Contractor may obtain copies from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:

(i) Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at *http://www.cdc.gov/biosafety/publications/index.htm*.

(ii) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street NW., Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication is available at *http://www.nap.edu/catalog/4911/prudent-practices-in-the-laboratory-han...*.

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the

Contracting Officer, in conjunction with the Contracting Officer's Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable “Changes” clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report citing all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall form the basis for a request for extension or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

352.223-71 Instructions to Offerors—Sustainable Acquisition.

As prescribed in HHSAR 323.7103, the Contracting Officer shall insert the following provision:

Instructions to Offerors—Sustainable Acquisition (DEC 2015)

Offerors must include a Sustainable Acquisition Plan in their technical proposals. The Plan must describe their approach and the quality assurance mechanisms in place for applying FAR 23.1, Sustainable Acquisition Policy (and other Federal laws, regulations and Executive Orders governing sustainable acquisition purchasing) to this acquisition. The Plan shall clearly identify those products and services included in Federal sustainable acquisition preference programs by categorizing them along with their respective price/cost in the following eight groups: Recycled Content, Energy Efficient, Biobased, Environmentally Preferable, Electronic Product Environment Assessment Tool, Water-Efficient, Non-Ozone Depleting Substances, and Alternative Fuel Vehicle and Alternative Fuels.

(End of provision)

352.224-70 Privacy Act.

As prescribed in HHSAR 324.105(a), the Contracting Officer shall insert the following clause:

Privacy Act (DEC 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 45 CFR 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)

352.224-71 Confidential Information.

As prescribed in HHSAR 324.105(b), insert the following clause:

Confidential Information (DEC 2015)

(a) Confidential Information, as used in this clause, 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) Specific information or categories of information that the Government will furnish to the Contractor, or that the Contractor is expected to generate, which are confidential may be identified elsewhere in this contract. The Contracting Officer may modify this contract to identify Confidential Information from time to time during performance.

(c) Confidential Information or records shall not be disclosed by the Contractor until:

(1) Written advance notice of at least 45 days shall be provided to the Contracting Officer of the

Contractor's intent to release findings of studies or research, to which an agency response may be appropriate to protect the public interest or that of the agency.

(2) For information provided by or on behalf of the government,

(i) The publication or dissemination of the following types of information are restricted under this contract: [INSERT RESTRICTED TYPES OF INFORMATION. IF NONE, SO STATE.]

(ii) The reason(s) for restricting the types of information identified in subparagraph (i) is/are: [STATE WHY THE PUBLIC OR GOVERNMENT INTEREST REQUIRES THE RESTRICTION OF EACH TYPE OF INFORMATION. ANY BASIS FOR NONDISCLOSURE WHICH WOULD BE VALID UNDER THE FREEDOM OF INFORMATION ACT IS SUFFICIENT UNDER THIS CLAUSE.]

(iii) Written advance notice of at least 45 days shall be provided to the Contracting Officer of the Contractor's intent to disseminate or publish information identified in subparagraph (2)(i). The contractor shall not disseminate or publish such information without the written consent of the Contracting Officer.

(d) Whenever the Contractor is uncertain with regard to the confidentiality of or a property interest in information under this contract, the Contractor should consult with the Contracting Officer prior to any release, disclosure, dissemination, or publication.

352.226-1 Indian Preference.

As prescribed in HHSAR 326.505(a), the Contracting Officer shall insert the following clause:

Indian Preference (DEC 2015)

(a) The Contractor agrees to give preference in employment opportunities under this contract to Indians who can perform required work, regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation. To the extent feasible and consistent with the efficient performance of this contract, the Contractor further agrees to give preference in employment and training opportunities under this contract to Indians who are not fully qualified to perform regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation. The Contractor also agrees to give preference to Indian organizations and Indian-owned economic enterprises in the awarding of any subcontracts to the extent feasible and consistent with the efficient performance of this contract. The Contractor shall maintain the necessary statistical records to demonstrate compliance with this paragraph.

(b) In connection with the Indian employment preference requirements of this clause, the Contractor shall provide reasonable opportunities for training, incident to such employment. Such training shall include on-the-job, classroom, or apprenticeship training designed to increase the vocational effectiveness of an Indian employee.

(c) If the Contractor is unable to fill its employment and training opportunities after giving full consideration to Indians as required by this clause, the Contractor may satisfy those needs by selecting non-Indian persons in accordance with the clause of this contract entitled “Equal Opportunity.”

(d) If no Indian organizations or Indian-owned economic enterprises are available under reasonable terms and conditions, including price, for awarding of subcontracts in connection with the work

performed under this contract, the Contractor agrees to comply with the provisions of this contract involving utilization of small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; women-owned small businesses; or small disadvantaged businesses.

(e) As used in this clause,

(1) *Indian* means a person who is a member of an Indian tribe. If the Contractor has reason to doubt that a person seeking employment preference is an Indian, the Contractor shall grant the preference but shall require the individual provide evidence within 30 days from the tribe concerned that the person is a member of the tribe.

(2) *Indian tribe* means an Indian tribe, pueblo, band, nation, or other organized group or community, including Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601) which the United States recognizes as eligible for the special programs and services provided to Indians because of its status as Indians.

(3) *Indian organization* means the governing body of any Indian Tribe or entity established or recognized by such governing body in accordance with the Indian Financing Act of 1974 (88 Stat. 77; 25 U.S.C. 1451).

(4) *Indian-owned economic enterprise* means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and that ownership shall encompass active operation and control of the enterprise.

(f) The Contractor agrees to include the provisions of this clause, including this paragraph (f) of this clause, in each subcontract awarded at any tier under this contract.

(g) In the event of noncompliance with this clause, the Contracting Officer may terminate the contract in whole or in part or may pursue any other remedies authorized by law or by other provisions of the contract.

(End of clause)

352.226-2 Indian Preference Program.

As prescribed in HHSAR 326.505(b), the Contracting Officer shall insert the following clause:

Indian Preference Program (DEC 2015)

(a) In addition to the requirements of the clause of this contract entitled “Indian Preference,” the Contractor agrees to establish and conduct an Indian preference program which will expand opportunities for Indians to receive preference for employment and training in connection with the work performed under this contract, and which will expand the opportunities for Indian organizations and Indian-owned economic enterprises to receive a preference in the awarding of subcontracts. In this connection, the Contractor shall perform the following:

(1) Designate a liaison officer who will maintain liaison with the Government and the Tribe(s) on Indian preference matters; supervise compliance with the provisions of this clause; and administer

the Contractor's Indian preference program.

(2) Advise its recruitment sources in writing and include a statement in all employment advertisements that Indian applicants receive preference in employment and training incident to such employment.

(3) Not more than 20 calendar days after award of the contract, post a written notice setting forth the Contractor's employment needs and related training opportunities in the tribal office of any reservations on or near the contract work location. The notice shall include the approximate numbers and types of employees needed; the approximate dates of employment; any experience or special skills required for employment; training opportunities available; and other pertinent information necessary to advise prospective employees of any other employment requirements. The Contractor shall also request the tribe(s) on or near whose reservation(s) the Contractor will perform contract work to provide assistance filling its employment needs and training opportunities. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to contact regarding the posting of notices and requests for Tribal assistance.

(4) Establish and conduct a subcontracting program which gives preference to Indian organizations and Indian-owned economic enterprises as subcontractors (including suppliers) under this contract. The Contractor shall give public notice of existing subcontracting opportunities and, to the extent feasible and consistent with the efficient performance of this contract, shall solicit bids or proposals from Indian organizations or Indian-owned economic enterprises only. The Contractor shall request assistance and information on Indian firms qualified as subcontractors (including suppliers) from the Tribe(s) on or near whose reservation(s) the Contractor will perform contract work. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to contact regarding the request for assistance and information. Public notices and solicitations for existing subcontracting opportunities shall provide an equitable opportunity for Indian firms to submit bids or proposals by including—

(i) A clear description of the supplies or services required, including quantities, specifications, and delivery schedules that facilitate the participation of Indian firms;

(ii) A statement indicating that Indian organizations and Indian-owned economic enterprises will receive preference in accordance with section 7(b) of Public Law 93-638; 88 Stat. 2205; 25 U.S.C. 450e(b);

(iii) Definitions for the terms “Indian organization” and “Indian-owned economic enterprise” prescribed under the “Indian Preference” clause of this contract;

(iv) A statement that the bidder or offeror shall complete certifying that it is an Indian organization or Indian-owned economic enterprise; and

(v) A closing date for receipt of bids or proposals which provides sufficient time for preparation and submission of a bid or proposal. If, after soliciting bids or proposals from Indian organizations and Indian-owned economic enterprises, the Contractor receives no responsive bid or acceptable proposal, the Contractor shall comply with the requirements of paragraph (d) of the “Indian Preference” clause of this contract. If the Contractor receives one or more responsive bids or conforming proposals, the Contractor shall award the contract to the low, responsive, responsible bidder or conforming offer from a responsible offeror if the price is reasonable. If the Contractor determines the low responsive bid or conforming proposal's price is unreasonable, the Contractor shall attempt to negotiate a reasonable price and award a subcontract. If parties cannot agree on a reasonable price, the Contractor shall comply with the requirements of paragraph (d) of the “Indian

Preference" clause of this contract.

(5) Maintain written records under this contract which demonstrate—

(i) The numbers of Indians seeking employment for each employment position available under this contract;

(ii) The number and types of positions filled by Indians and non-Indians;

(iii) The total number of Indians employed under this contract;

(iv) For those positions having both Indian and non-Indian applicants, and a non-Indian is selected for employment, the reason(s) why the Contractor did not select the Indian applicant;

(v) Actions taken to give preference to Indian organizations and Indian-owned economic enterprises for subcontracting opportunities which exist under this contract;

(vi) Reasons why Indian subcontractors and or suppliers did not receive preference for each requirement where the Contractor determined that such preference was inconsistent with efficient contract performance; and

(vii) The number of Indian organizations and Indian-owned economic enterprises contacted, and the number receiving subcontract awards under this contract.

(6) Submit to the Contracting Officer for approval a quarterly report summarizing the Contractor's Indian preference program and indicating the number and types of available positions filled by Indians and non-Indians, and the dollar amounts of all subcontracts awarded to Indian organizations and Indian-owned economic enterprises, and to all other firms.

(7) Maintain records pursuant to this clause and keep them available for review by the Government for one year after final payment under this contract, or for such longer period in accordance with requirements of any other clause of this contract or by applicable law or regulation.

(b) For purposes of this clause, the following definitions of terms shall apply:

(1) The terms *Indian, Indian tribe, Indian organization,* and *Indian-owned economic enterprise* are defined in the clause of this contract entitled *Indian Preference.*

(2) *Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601 *et seq.*)

(3) *On or near an Indian reservation* means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably expect to commute to and from in the course of a work day.

(c) Nothing in the requirements of this clause shall preclude Indian tribes from independently developing and enforcing their own Indian preference requirements. Such requirements must not conflict with any Federal statutory or regulatory requirement dealing with the award and administration of contracts.

(d) The Contractor agrees to include the provisions of this clause, including this paragraph (d), in

each subcontract awarded at any tier under this contract and to notify the Contracting Officer of such subcontracts.

(e) In the event of noncompliance with this clause, the Contracting Officer may terminate the contract in whole or in part or may pursue any other remedies authorized by law or by other provisions of the contract.

(End of clause)

352.226-3 Native American Graves Protection and Repatriation Act.

As prescribed in HHSAR 326.701, the Contracting Officer shall insert the following clause:

Native American Graves Protection and Repatriation Act (DEC 2015)

(a) Public Law 101-601, dated November 16, 1990, also known as the Native American Graves Protection and Repatriation Act, imposes certain responsibilities on individuals and organizations when they discover Native American cultural items (including human remains) on Federal or tribal lands.

(b) In the event the Contractor discovers Native American cultural items (including human remains, associated funerary objects, unassociated funerary objects, sacred objects and cultural patrimony), as defined in the Act during contract performance, the Contractor shall—

(1) Immediately cease activity in the area of the discovery;

(2) Notify the Contracting Officer of the discovery; and

(3) Make a reasonable effort to protect the items discovered before resuming such activity. Upon receipt of the Contractor's discovery notice, the Contracting Officer will notify the appropriate authorities as required by the Act.

(c) Unless otherwise specified by the Contracting Officer, the Contractor may resume activity in the area on the 31st calendar day following the date that the appropriate authorities certify receipt of the discovery notice. The Contracting Officer shall provide to the Contractor the date that the appropriate authorities certify receipt of the discovery notice and the date on which the Contractor may resume activities.

352.226-4 Notice of Indian Small Business Economic Enterprise set-aside.

As prescribed in HHSAR 326.604-2(b)(1), and in lieu of the requirements of 48 CFR 19.508, the Contracting Officer shall insert the following provision:

Notice of Indian Small Business Economic Enterprise Set-Aside

Under the Buy Indian Act, 25 U.S.C. 47, offers are solicited only from Indian Economic Enterprises (HHSAR 326.606) that are also small business concerns. Any acquisition resulting from this solicitation will be from such a concern. As required by HHSAR § 352.226-7(b), offerors shall include a completed Indian Economic Enterprise Representation form in response to Sources Sought Notices, Request for Information (RFI) and as part of the proposal submission. The Indian Economic

Enterprise Representation form, available on the IHS DAP public website (*www.IHS.gov/DAP*), shall be included in synopses, presolicitation notices, and solicitations for the acquisitions under the Buy Indian Act. Offers received from enterprises that are not both Indian Economic Enterprises and small business concerns will not be considered and will be rejected.

(End of clause)

352.226-5 Notice of Indian Economic Enterprise set-aside.

As prescribed in HHSAR 326.604-2(e)(2), the Contracting Officer shall insert the following clause:

Notice of Indian Economic Enterprise Set-Aside

(a) *Definitions as used in this clause:*

Alaska Native Claims Settlement Act (ANCSA) means Public Law 92-203 (December 18, 1971), 85 Stat. 688, codified at 43 U.S.C. 1601-1629h.

Indian means a person who is an enrolled member of an Indian Tribe or "Native" as defined in the Alaska Native Claims Settlement Act.

Indian Economic Enterprise means any business activity owned by one or more Indians or Indian Tribes that is established for the purpose of profit provided that: The combined Indian or Indian Tribe ownership must constitute not less than 51 percent of the enterprise; the Indians or Indian Tribes must, together, receive at least a majority of the earnings from the contract; and the management and daily business operations of an enterprise must be controlled by one or more individuals who are Indians. To ensure actual control over the enterprise, the individuals must possess requisite management or technical capabilities directly related to the primary industry in which the enterprise conducts business. The enterprise must meet these requirements throughout the following time periods:

(i) At the time an offer is made in response to a written solicitation;

(ii) At the time of the contract award; and

(iii) During the full term of the contract.

Indian Tribe means an Indian Tribe, band, nation, or other recognized group or community that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians, including any Alaska Native village or regional or village corporation under the Alaska Native Claims Settlement Act (Pub. L. 92-203, 85 Stat. 688; 43 U.S.C. 1601).

Representation means the positive statement by an enterprise of its eligibility for preferential consideration and participation for acquisitions conducted under the Buy Indian Act, 25 U.S.C. 47, in accordance with the procedures in Subpart 326.606.

(b) *General.*

(1) Under the Buy Indian Act, offers are solicited only from Indian Economic Enterprises.

(2) The CO will reject all offers received from ineligible enterprises.

(3) Any award resulting from this solicitation will be made to an Indian Economic Enterprise, as defined in paragraph (a) of this clause.

(c) *Required submissions.* In response to this solicitation, an offeror must also provide the following:

(1) A description of the required percentage of the work/costs to be provided by the offeror over the contract term as required by section 352.226-6, Subcontracting Limitations clause; and

(2) Qualifications of the key personnel (if any) that will be assigned to the contract.

(d) Required assurance. The offeror must provide written assurance to the CO that the offeror is and will remain in compliance with the requirements of this clause. It must do this before the CO awards the Buy Indian Act contract and upon successful and timely completion of the contract, but before the CO accepts the work or product.

(e) Non-responsiveness. Failure to provide the information required by paragraphs (c) and (d) of this clause may cause the CO to find an offer non-responsive and reject it.

(f) Eligibility.

(1) Participation in the Mentor-Protégé Program established under section 831 of the National Defense Authorization Act for Fiscal Year 1991 (25 U.S.C. 47 note) does not render an Indian Economic Enterprise ineligible for contracts awarded under the Buy Indian Act.

(2) If a contractor no longer meets the definition of an Indian Economic Enterprise after award, the contractor must notify the CO immediately and in writing. The notification must include full disclosure of circumstances causing the contractor to lose eligibility status and a description of any actions that the contractor will take to regain eligibility. Failure to give the CO immediate written notification means that:

(i) The economic enterprise may be declared ineligible for future contract awards under this part; and

(ii) The CO may consider termination for default if it is in the best interest of the government.

(g) Representation. Under the Buy Indian Act, 25 U.S.C. 47, offers are solicited only from Indian Economic Enterprises (326.606). As required by HHSAR 352.226-7(b), offerors shall include a completed Indian Economic Enterprise Representation form in response to Sources Sought Notices, Request for Information (RFI) and as part of the proposal submission. The Indian Economic Enterprise Representation form, available on the IHS DAP public website (*www.IHS.gov/DAP*), shall be included in synopses, presolicitation notices, and solicitations for the acquisitions under the Buy Indian Act. Offers received from enterprises that are not Indian Economic Enterprises shall not be considered.

(End of clause)

352.226-6 Indian Economic Enterprise Subcontracting Limitations

As prescribed in HHSAR 326.604-2(e)(3), the Contracting Officer shall insert the following clause:

Indian Economic Enterprise Subcontracting Limitations

(a) Definitions as used in this clause.

(1) *Indian Economic Enterprise* means any business activity owned by one or more Indians or Indian Tribes that is established for the purpose of profit provided that: The combined Indian or Indian Tribe ownership must constitute not less than 51 percent of the enterprise; the Indians or Indian Tribes must, together, receive at least a majority of the earnings from the contract; and the management and daily business operations of an enterprise must be controlled by one or more individuals who are Indians. To ensure actual control over the enterprise, the individuals must possess requisite management or technical capabilities directly related to the primary industry in which the enterprise conducts business. The enterprise must meet these requirements throughout the following time periods:

(i) At the time an offer is made in response to a written solicitation;

(ii) At the time of the contract award; and

(iii) During the full term of the contract.

(2) *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 contractor or subcontractor. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(3) *Subcontractor* means any supplier, distributor, vendor, or firm that furnishes supplies or services to or for a prime contractor or another subcontractor.

(b) Required Percentages of work by the concern. The contractor must comply with FAR 52.219-14, Limitations on Subcontracting clause in allocating what percentage of work to subcontract. The contractor shall not subcontract work exceeding the subcontract limitations in FAR 52.219-14 to a concern other than a responsible Indian Economic Enterprise.

(c) Any work that an IEE subcontractor does not perform with its own employee shall be considered subcontracted work for the purpose of calculating percentages of subcontract work in accordance with FAR 52.219-14 Limitations on Subcontracting.

(d) Cooperation. The contractor must:

(1) Carry out the requirements of this clause to the fullest extent; and

(2) Cooperate in any study or survey that the CO, Indian Health Service or its agents may conduct to verify the contractor's compliance with this clause.

(e) Incorporation in Subcontracts. The contractor must incorporate the substance of this clause, including this paragraph (e), in all subcontracts for general services, A&E services and construction awarded under this contract.

(End of clause)

352.226-7 Indian Economic Enterprise Representation.

As prescribed in HHSAR 326.604-2(e)(4), the Contracting Officer shall insert the following provision:

Indian Economic Enterprise Representation

(a) The offeror must represent as part of its offer that it does meet the definition of Indian Economic Enterprise (IEE) as defined in HHSAR 326.601 and that it intends to meet the definition of an IEE throughout the performance of the contract. The offeror must notify the contracting officer immediately, via email, if there is any ownership change affecting compliance with this representation.

(b) The representation must be made on the designated IHS Indian Economic Enterprise Representation form or any successor forms through which the offeror will certify that the ownership requirements defined by HHSAR 326.601 are met.

(c) Any false or misleading information submitted by an enterprise when submitting an offer in consideration for an award set-aside under the Buy Indian Act is a violation of the law punishable under 18 U.S.C. 1001. False claims submitted as part of contract performance are subject to the penalties enumerated in 31 U.S.C. 3729 to 3731 and 18 U.S.C. 287.

(End of provision)

352.227-11 Patent Rights—Exceptional Circumstances.

As prescribed in HHSAR 327.303, the Contracting Officer shall insert the following clause:

Patent Rights—Exceptional Circumstances (SEPT 2014)

This clause applies to all Contractor and subcontractor (at all tiers) Subject Inventions.

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

Agency means the Agency of the U.S. Department of Health and Human Services that is entering into this contract.

Class 1 Subject Invention means a Subject Invention described and defined in the DEC that will be assigned to a third party assignee, or assigned as directed by the Agency.

Class 2 Subject Invention means a Subject Invention described and defined in the DEC.

Class 3 Subject Invention means a Subject Invention that does not fall into Class 1 or Class 2 as defined in this clause.

DEC means the Determination of Exceptional Circumstances signed by [insert approving official] _____ on ____ [insert date] _____ and titled "[insert description]."

Invention means any invention or discovery, which is or may be patentable or otherwise protectable under Title 35 of United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, *et seq.*)

Made means: When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of such invention; or when used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Material means any proprietary material, method, product, composition, compound, or device, whether patented or unpatented, which is provided to the Contractor under this contract.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

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

Small business firm means a small business concern as defined at section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

Subject Invention means any invention of the Contractor made in the performance of work under this contract.

Third party assignee means any entity or organization that may, as described in the DEC, be assigned Class 1 inventions.

(b) *Allocation of principal rights.*

(1) *Retention of pre-existing rights.* Third party assignees shall retain all preexisting rights to Material in which the Third party assignee has a proprietary interest.

(2) *Allocation of Subject Invention rights.*

(i) *Disposition of Class 1 Subject Inventions.* (A) Assignment to the Third party assignee or as directed by the Agency. The Contractor shall assign to the Third party assignee designated by the Agency the entire right, title, and interest throughout the world to each Subject Invention, or otherwise dispose of or transfer those rights as directed by the Agency, except to the extent that rights are retained by the Contractor under paragraph (b)(3) of this clause. Any such assignment or other disposition or transfer of rights will be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the U.S. Government to practice or have practiced the Subject Invention for or on behalf of the U.S. throughout the world. Any assignment shall additionally be subject to the "March-in rights" of 35 U.S.C. 203. If the Contractor is a U.S. nonprofit organization it may retain a royalty free, nonexclusive, nontransferable license to practice the invention for all nonprofit research including for educational purposes, and to permit other U.S. nonprofit organizations to do so.

(B) [Reserved]

(ii) *Disposition of Class 2 and 3 Subject Inventions.* Class 2 Subject Inventions shall be governed by FAR clause 52.227-11, Patent Rights-Ownership (December 2007) (incorporated herein by reference). However, the Contractor shall grant a license in the Class 2 Subject Inventions to the provider of the Material or other party designated by the Agency as set forth in Alternate I.

(iii) Class 3 Subject Inventions shall be governed by FAR clause 52.227-11, Patent Rights—Ownership by the Contractor (December 2007) (previously incorporated herein by reference).

(3) *Greater Rights Determinations.* The Contractor, or an employee-inventor after consultation by the Agency with the Contractor, may request greater rights than are provided in paragraph (b)(1) of this clause in accordance with the procedures of FAR paragraph 27.304-1(c). In addition to the considerations set forth in paragraph 27.304-1(c), the Agency may consider whether granting the requested greater rights will interfere with rights of the Government or any Third party assignee or otherwise impede the ability of the Government or the Third party assignee to, for example, develop and commercialize new compounds, dosage forms, therapies, preventative measures, technologies, or other approaches with potential for the diagnosis, prognosis, prevention, and treatment of human diseases.

A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Agency Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (c)(1) of this clause, or not later than 8 months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227-13 (incorporated herein by reference), and to any reservations and conditions deemed to be appropriate by the Agency such as the requirement to assign or exclusively license the rights to Subject Inventions to the Third party assignee.

A determination by the Agency denying a request by the Contractor for greater rights in a Subject Invention may be appealed within 30 days of the date the Contractor is notified of the determination to an Agency official at a level above the individual who made the determination. If greater rights are granted, the Contractor must file a patent application on the invention. Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any Subject Invention in any country for which the Contractor has retained title. Upon request, the Contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(c) *Invention disclosure by Contractor.* The Contractor shall disclose in writing each Subject Invention to the Agency Contracting Officer and to the Director, Division of Extramural Inventions and Technology Resources (DEITR), if directed by the Contracting Officer, as provided in paragraph (j) of this clause within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure to the Agency Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was Made and all inventors. It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication, and if so, whether it has been accepted for publication at the time of disclosure.

In addition, after disclosure to the Agency, the Contractor will promptly notify the Contracting Officer and DEITR of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the Contractor. If the Contractor assigns a Subject Invention to the Third party assignee, then the Contractor and its employee inventors shall assist the Third party assignee in securing patent protection. All costs of securing the patent, including the cost of the Contractor's assistance, are at the Third party's expense. Any assistance provided by the Contractor and its employee inventors to the Third party assignee or other costs incurred in securing patent protection shall be solely at the Third party's expense and not billable to the contract.

(d) *Contractor action to protect the Third party assignee's and the Government's interest.*

(1) The Contractor agrees to execute or to have executed and promptly deliver to the Agency all instruments necessary to: Establish or confirm the rights the Government has throughout the world in Subject Inventions pursuant to paragraph (b) of this clause; convey title to a Third party assignee in accordance with paragraph (b) of this clause; and enable the Third party assignee to obtain patent protection throughout the world in that Subject Invention.

(2) The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each Subject Invention "Made" under contract in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on Subject Inventions and to establish the Government's rights or a Third party assignee's rights in the Subject Inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) If the Contractor is granted greater rights, the Contractor agrees to include, within the specification of any United States non-provisional patent application it files, and any patent issuing thereon, covering a Subject Invention the following statement: "This invention was made with Government support under (identify the Contract) awarded by (identify the specific Agency). The Government has certain rights in the invention."

(4) The Contractor agrees to provide a final invention statement and certification prior to the closeout of the contract listing all Subject Inventions or stating that there were none.

(e) *Subcontracts.*

(1) The Contractor will include this clause in all subcontracts, regardless of tier, for experimental, developmental, or research work. At all tiers, the clause must be modified to identify the parties as follows: References to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor will not, as part of the consideration for awarding the contract, obtain rights in the subcontractor's Subject Inventions.

(2) In subcontracts, at any tier, the Agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (c)(1)(ii) of FAR clause 52.227-13.

(f) *Reporting on utilization of Subject Inventions in the event greater rights are granted to the Contractor.* The Contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request under subparagraph b.3. has been granted by the Agency. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and such other data and information as the Agency may reasonably specify. The Contractor also agrees to provide additional reports as may be requested by the Agency in connection with any march-in proceeding undertaken by the Agency in accordance with paragraph (h) of this clause. As required

by 35 U.S.C. 202(c)(5), the Agency agrees it will not disclose such information to persons outside the Government without permission of the Contractor.

(g) Preference for United States industry in the event greater rights are granted to the Contractor. Notwithstanding any other provision of this clause, the Contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(h) *March-in rights in the event greater rights are granted to the Contractor.* The Contractor acknowledges that, with respect to any Subject Invention in which it has acquired ownership through the exercise of the rights specified in paragraph (b)(3) of this clause, the Agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of Agency in effect on the date of contract award.

(i) *Special provisions for contracts with nonprofit organizations in the event greater rights are granted to the Contractor.* If the Contractor is a nonprofit organization, it shall:

(1) Not assign rights to a Subject Invention in the United States without the written approval of the Agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a Subject Invention with the inventor, including Federal employee co-inventors (but through their Agency if the Agency deems it appropriate) when the Subject Invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to Subject Inventions, after payment of expenses (including payments to inventors) incidental to the administration of Subject Inventions for the support of scientific research or education;

(4) Make efforts that are reasonable under the circumstances to attract licensees of Subject Inventions that are small business concerns, and give a preference to a small business concern when licensing a Subject Invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor; and

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) *Communications.* All invention disclosures and requests for greater rights shall be sent to the Agency Contracting Officer, as directed by the Contracting Officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications under this funding agreement at all tiers must be sent to:

[Insert Agency Address]

Agency Invention Reporting Web site: *https://public.era.nih.gov/iedison*.

Alternate I (Sept 2014). As prescribed in 327.303, the license to Class 2 inventions recited in 352.227-11(b)(2)(a) is as follows:

[Insert description of license to Class 2 inventions]

(End of clause)

352.227-14 Rights in Data—Exceptional Circumstances.

As prescribed in HHSAR 327.409, insert the following clause with any appropriate alternates:

Rights in Data—Exceptional Circumstances (SEPT 2014)

(a) *Definitions.* As used in this clause—Definitions may be added or modified in paragraph (a) as applicable.

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. 253d, 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 HHSAR 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 HHSAR *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. ____ (and subcontract ____, 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 HHSAR 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. ____ (and subcontract ____, 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. ____ (and subcontract, if appropriate) with ____ (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 HHSAR 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 HHSAR 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.

(End of clause)

352.227-70 Publications and Publicity.

As prescribed in HHSAR 327.404-70, the Contracting Officer shall insert the following clause:

Publications and Publicity (DEC 2015)

(a) Unless otherwise specified in this contract, the Contractor may publish the results of its work

under this contract. The Contractor shall promptly send a copy of each article submitted for publication to the Contracting Officer's Representative. The Contractor shall also inform the Contracting Officer's Representative when the article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the Contracting Officer, the Contractor shall not display the HHS logo including Operating Division or Staff Division logos on any publications.

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

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract.

(End of clause)

352.231-70 Salary Rate Limitation.

As prescribed in HHSAR 331.101-70(b), the Contracting Officer shall insert the following clause:

Salary Rate Limitation (DEC 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.

(b) For purposes of the salary rate limitation, the terms “direct salary,” “salary,” and “institutional base salary,” have the same meaning and are collectively referred to as “direct salary,” in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

(e) See the salaries and wages pay tables on the Office of Personnel Management Web site for Federal Executive Schedule salary levels.

(End of clause)

352.232-70 Incremental Funding.

As prescribed in HHSAR 332.706-2(b), the Contracting Officer shall insert the provision provided

below in all solicitations when a cost-reimbursement contract for severable services using incremental funding is contemplated.

Incremental Funding (DEC 2015)

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clause at FAR 52.232-22, “Limitation of Funds”. The initial obligation of funds under the contract is expected to cover [*insert the appropriate increment of performance*]. The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining periods of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision)

352.232-71 Electronic submission of payment requests

As prescribed in HHSAR 332.7003, use the following clause:

Electronic Submission of Payment Requests

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

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), “Content of Invoices” and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at *www.ipp.gov* or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(End of Clause)

352.233-70 Choice of Law (Overseas).

As prescribed in HHSAR 333.215-70(a), the Contracting Officer shall insert the following clause:

Choice of Law (Overseas) (DEC 2015)

This contract shall be construed in accordance with the substantive laws of the United States of America. By the execution of this contract, the Contractor expressly agrees to waive any rights to

invoke the jurisdiction of local national courts where this contract is performed and agrees to accept the exclusive jurisdiction of the United States Civilian Board of Contract Appeals or the United States Court of Federal Claims for hearing and determination of any and all disputes that may arise under the Disputes clause of this contract.

(End of clause)

352.233-71 Litigation and Claims.

As prescribed in HHSAR 333.215-70(b), the Contracting Officer shall insert the following clause:

Litigation and Claims (DEC 2015)

(a) The Contractor shall provide written notification immediately to the Contracting Officer of any action, including any proceeding before an administrative agency, filed against the Contractor arising out of the performance of this contract, including, but not limited to the performance of any subcontract hereunder; and any claim against the Contractor the cost and expense of which is allowable under the clause entitled “Allowable Cost and Payment.”

(b) Except as otherwise directed by the Contracting Officer, the Contractor shall furnish immediately to the Contracting Officer copies of all pertinent documents received by the Contractor with respect to such action or claim. To the extent not in conflict with any applicable policy of insurance, the Contractor may, with the Contracting Officer's approval, settle any such action or claim. If required by the Contracting Officer, the Contractor shall effect an assignment and subrogation in favor of the Government of all the Contractor's rights and claims (except those against the Government) arising out of any such action or claim against the Contractor; and authorize representatives of the Government to settle or defend any such action or claim and to represent the Contractor in, or to take charge of, any action.

(c) If the Government undertakes a settlement or defense of an action or claim, the Contractor shall furnish all reasonable assistance in effecting a settlement or asserting a defense. Where an action against the Contractor is not covered by a policy of insurance, the Contractor shall, with the approval of the Contracting Officer, proceed with the defense of the action in good faith. The Government shall not be liable for the expense of defending any action or for any costs resulting from the loss thereof to the extent that the Contractor would have been compensated by insurance which was required by other terms or conditions of this contract, by law or regulation, or by written direction of the Contracting Officer, but which the Contractor failed to secure through its own fault or negligence. In any event, unless otherwise expressly provided in this contract, the Government shall not reimburse or indemnify the Contractor for any liability loss, cost, or expense, which the Contractor may incur or be subject to by reason of any loss, injury or damage, to the person or to real or personal property of any third parties as may accrue during, or arise from, the performance of this contract.

(End of clause)

352.236-70 Design-Build Contracts.

As prescribed in HHSAR 336.570(a), the Contracting Officer shall insert the following clause:

Design-Build Contracts (DEC 2015)

(a) *General.*

(1) The contract constitutes and defines the entire agreement between the Contractor and the Government. This contract includes the standard or special contract clauses and schedules included at the time of award. This contract incorporates by reference:

(i) The solicitation in its entirety (with the exception of instructions to offerors and evaluation criteria which do not become part of the award document);

(ii) The specifications and statement of work;

(iii) All drawings, cuts and illustrations, included in the solicitation and any amendments during all proposal phases leading up to award;

(iv) Exhibits and other attachments; and

(v) The successful Offeror's accepted proposal.

(2) In the event of conflict or inconsistency between any of the requirements of the various portions of this contract, precedence shall be given in the following order:

(i) Betterments: Any portions of the Offeror's proposal which exceed the requirements of the solicitation and which go beyond repair and improve the value of the property.

(ii) The contract clauses and schedules included during the solicitation or at the time of award.

(iii) All requirements (other than betterments) of the accepted proposal.

(iv) Any design products, including but not limited to plans, specifications, engineering studies and analyses, shop drawings, equipment installation drawings, *etc.* These are “deliverables” under the contract and are not part of the contract itself.

(3) Design products must conform to all requirements of the contract, in the order of precedence stated here.

(b) *Responsibility of the contractor for design.*

(1) The Contractor shall be responsible for the professional quality, technical accuracy, and the coordination of all designs, drawings, specifications, and other non-construction services furnished by the Contractor under this contract. The Contractor shall, without additional compensation, correct or revise any errors or deficiency in its designs, drawings, specifications, and other non-construction services and perform any necessary rework or modifications, including any damage to real or personal property, resulting from the design error or omission.

(2) Neither the Government's review, approval or acceptance of, nor payment for, the services required under this contract shall be construed to operate as a waiver of any rights under this contract or of any cause of action arising out of the performance of this contract. The Contractor shall be and remain liable to the Government in accordance with applicable law for all damages to the Government caused by the Contractor's negligent performance of any of these services furnished under this contract.

(3) The rights and remedies of the Government provided for under this contract are in addition to

any other rights and remedies provided by law.

(4) If the Contractor is comprised of more than one legal entity each such entity shall be jointly and severally liable with respect to all rights and remedies of the Government.

(c) *Sequence of design—construction.*

(1) After receipt of the Contract Award, the Contractor shall initiate design, comply with all design submission requirements, and obtain Government review of each submission. No construction may be started until the Government reviews the Final Design submission and determines it satisfactory for purposes of beginning construction. The Contracting Officer will notify the Contractor when the design is cleared for construction. The Government will not grant any time extension for any design resubmittal required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

(2) If the Government allows the Contractor to proceed with limited construction based on pending minor revisions to the reviewed Final Design submission, no payment will be made for any completed or in-progress construction related to the pending revisions until they are completed, resubmitted, and are satisfactory to the Government.

(3) No payment will be made for any completed or in-progress construction until all required submittals have been made, reviewed, and are satisfactory to the Government.

(d) *Constructor's role during design.* The Contractor's construction management key personnel shall be actively involved during the design process to effectively integrate the design and construction requirements of this contract. In addition to the typical required construction activities, the constructor's involvement includes, but is not limited to actions such as: integrating the design schedule into the Master Schedule to maximize the effectiveness of fast-tracking design and construction (within the limits, if any, allowed in the contract), ensuring constructability and economy of the design, integrating the shop drawing and installation drawing process into the design, executing the material and equipment acquisition programs to meet critical schedules, effectively interfacing the construction Quality Control (QC) program with the design QC program, and maintaining and providing the design team with accurate, up-to-date redline and as-built documentation. The Contractor shall require and manage the active involvement of key trade subcontractors in the above activities.

(e) *Preconstruction conference.*

(1) A preconstruction conference will be arranged by the Contracting Officer after award of contract and before commencement of work. The Contracting Officer or designated representative will notify the Contractor of the time, date, and location for the meeting. At this conference, the Contractor shall be oriented with respect to Government procedures and line of authority, contractual, administrative, and construction matters.

(2) The Contractor shall bring to this conference, in completed form, a Certificate of Insurance, plus the following items in either completed or draft form:

(i) Accident Prevention Plan;

(ii) Quality Control Plan;

(iii) Letter Appointing Superintendent;

(iv) Transmittal Register;

(v) Power of Attorney and Certified Copy of Resolution;

(vi) Network Analysis System, (when identified in the contract schedule as applicable);

(vii) List of Subcontractors;

(viii) SF 1413;

(ix) Performance and Payment Bonds; and

(x) Schedule of Values.

(3) A letter of record will be written documenting all items discussed at the conference, and a copy will be furnished by the Contracting Officer to all in attendance.

(f) *Payment for design under fixed-price design-build contracts.*

(1) The Contracting Officer may approve progress payments for work performed during the project design phase up to the maximum amount of ____ (*Contracting Officer to insert percent figure. If none stated, the amount is four (4) percent*) percent of the contract price.

(2) Contractor invoices for payment must be accompanied by satisfactory documentation supporting the amounts for which payments are requested. Progress payments approved by the Contracting Officer during the project design phase in no way constitute an acceptance of functional and aesthetic design elements nor acceptance of a final settlement amount in the event of a buy-out nor a waiver of any contractual requirements.

(g) *Unscheduled jobsite shutdowns.* Due to security reasons during the life of this contract the Government may on an unscheduled basis require the contractor to shut down its jobsite for 2 days per year at no additional cost. This shall not constitute a suspension of work under FAR 52.242-14, Suspension of Work

(End of clause)

Alternate I (DEC 2015).

When Fast Track procedures are being used, replace paragraph (c) of the basic clause with the following:

(c) *Sequence of design build.*

(1) After receipt of the Contract Award the Contractor shall initiate design, comply with all design submissions requirements and obtain Government review of each submission. The contractor may begin construction on portions of the work for which the Government has reviewed the final design submission and has determined satisfactory for purposes of beginning construction. The Contracting Officer will notify the Contractor when the design is cleared for construction. The Government will not grant any time extension for any design resubmittal required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

(2) If the Government allows the Contractor to proceed with the construction based on pending minor revisions to the reviewed Final Design submission, no payment will be made for any in-place

construction related to the pending revisions until they are completed, resubmitted, and are satisfactory to the Government.

(3) No payment will be made for any in-place construction until all required submittals have been made, reviewed, and are satisfactory to the Government.

(End of clause)

352.237-70 Pro-Children Act.

As prescribed in HHSAR 337.103(d)(1), the Contracting Officer shall insert the following clause:

Pro-Children Act (DEC 2015)

(a) Public Law 103-227, Title X, Part C, also known as the *Pro-Children Act of 1994* (Act), 20 U.S.C. 7183, imposes restrictions on smoking in facilities where certain federally funded children's services are provided. The Act prohibits smoking within any indoor facility (or portion thereof), whether owned, leased, or contracted for, that is used for the routine or regular provision of: (i) Kindergarten, elementary, or secondary education or library services or (ii) health or day care services that are provided to children under the age of 18. The statutory prohibition also applies to indoor facilities that are constructed, operated, or maintained with Federal funds.

(b) By acceptance of this contract or order, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all subcontracts awarded under this contract for the specified children's services. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act. Failure to comply with the Act may result in the imposition of a civil monetary penalty in an amount not to exceed $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity. Each day a violation continues constitutes a separate violation.

352.237-71 Crime Control Act—Reporting of Child Abuse.

As prescribed in HHSAR 337.103(d)(2), the Contracting Officer shall insert the following clause:

Crime Control Act of 1990—Reporting of Child Abuse (DEC 2015)

(a) Public Law 101-647, also known as the Crime Control Act of 1990 (Act), imposes responsibilities on certain individuals who, while engaged in a professional capacity or activity, as defined in the Act, on Federal land or in a federally-operated (or contracted) facility, learn of facts that give the individual reason to suspect that a child has suffered an incident of child abuse.

(b) The Act designates “covered professionals” as those persons engaged in professions and activities in eight different categories including, but not limited to, teachers, social workers, physicians, dentists, medical residents or interns, hospital personnel and administrators, nurses, health care practitioners, chiropractors, osteopaths, pharmacists, optometrists, podiatrists, emergency medical technicians, ambulance drivers, alcohol or drug treatment personnel, psychologists, psychiatrists, mental health professionals, child care workers and administrators, and commercial film and photo processors. The Act defines the term “child abuse” as the physical or mental injury, sexual abuse or exploitation, or negligent treatment of a child.

(c) Accordingly, any person engaged in a covered profession or activity under an HHS contract or subcontract, regardless of the purpose of the contract or subcontract, shall immediately report a suspected child abuse incident in accordance with the provisions of the Act. If a child is suspected of being harmed, the appropriate State Child Abuse Hotline, local child protective services (CPS), or law enforcement agency shall be contacted. For more information about where and how to file a report, the Childhelp USA, National Child Abuse Hotline (1-800-4-A-CHILD) shall be called. Any covered professional failing to make a timely report of such incident shall be guilty of a Class B misdemeanor.

(d) By acceptance of this contract or order, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all applicable subcontracts awarded under this contract. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act.

(End of clause)

352.237-72 Crime Control Act—Requirement for Background Checks.

As prescribed in HHSAR 337.103(d)(3), the Contracting Officer shall insert the following clause:

Crime Control Act of 1990—Requirement for Background Checks (DEC 2015)

(a) Public Law 101-647, also known as the Crime Control Act of 1990 (Act), requires that all individuals involved with the provision of child care services to children under the age of 18 undergo a criminal background check. “Child care services” include, but are not limited to, social services, health and mental health care, child (day) care, education (whether or not directly involved in teaching), and rehabilitative programs. Any conviction for a sex crime, an offense involving a child victim, or a drug felony, may be grounds for denying employment or for dismissal of an employee providing any of the services listed above.

(b) The Contracting Officer will provide the necessary information to the Contractor regarding the process for obtaining the background check. The Contractor may hire a staff person provisionally prior to the completion of a background check, if at all times prior to the receipt of the background check during which children are in the care of the newly-hired person, the person is within the sight and under the supervision of a previously investigated staff person.

(c) By acceptance of this contract or order, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all applicable subcontracts awarded under this contract. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act.

(End of clause)

352.237-73 Indian Child Protection and Family Violence Act.

As prescribed in HHSAR 337.103(d)(4) the Contracting Officer shall insert the following clause:

Indian Child Protection and Family Violence Act (DEC 2015)

(a) This contract is subject to the Indian Child Protection and Family Violence Act, Public Law

101-630 (25 U.S.C. 3201 *et seq.*) The duties and responsibilities required by this contract may involve regular contact with or control over Indian children. Public Law 101-630 prohibits employment, including Personal Service Contracts, with anyone who has been convicted of any crime of violence. Any such conviction should immediately be brought to the attention of the Contracting Officer. The contractor will be subject to a character investigation, conducted by the Indian Health Service, Office of Human Resources. Until such time as the contractor has been notified of completion of the investigation, the contractor shall have no unsupervised contact with Indian children. In order to initiate this background investigation, the contractor must provide information as required in this contract or as directed by the Contracting Officer.

(b) As a prerequisite to providing services under this contract, the Contractor is required to complete and sign the declaration found in Section J of this contract.

(End of clause)

352.237-74 Non-Discrimination in Service Delivery.

As prescribed in HHSAR 337.103(e), the Contracting Officer shall insert the following clause in solicitations and contracts:

Non-Discrimination In Service Delivery (DEC 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 sub-contracts 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)

352.237-75 Key Personnel.

As prescribed in HHSAR 337.103(f), the Contracting Officer shall insert the following clause:

Key Personnel (DEC 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)

352.239-73 Electronic Information and Technology Accessibility Notice.

(a) As prescribed in HHSAR 339.203-70(a), the Contracting Officer shall insert the following provision:

Electronic and Information Technology Accessibility Notice (DEC 2015)

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at *http://www.hhs.gov/web/508*. The complete text of the Section 508 Final Provisions can be accessed at *http://www.access-board.gov/guidelines-and-standards/communications-and…*.

(c) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document—in detail—whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site *http://www.hhs.gov/web/508*.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, *i.e.,* after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the

supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

352.239-74 Electronic and Information Technology Accessibility.

As prescribed in HHSAR 339.203-70(b), insert the following clause:

Electronic and Information Technology Accessibility (DEC 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…*.

(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.

(End of clause)

352.270-1-352.270-3 [Reserved]

352.270-4a Notice to Offerors, Protection of Human Subjects.

As prescribed in HHSAR 370.303(a), the Contracting Officer shall insert the following provision:

Notice to Offerors, Protection of Human Subjects (DEC 2015)

(a) The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) Web site at: *http://www.hhs.gov/ohrp/index.html*.

These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.

(c) Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.101(b)(1)-(6) are exempt from complying with 45 CFR part 46. See *http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html*.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.

(e) In accordance with 45 CFR part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111 for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at *http://www.hhs.gov/ohrp/assurances/index.html*).

(f) Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the contracting officer may offer information concerning a solicitation.

(g) The offeror shall document in its proposal the approved FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research. If the offeror does not have an approved FWA from OHRP, the offeror must obtain an FWA before the deadline for proposal submission. When possible, the offeror shall also certify the IRB's review and approval of the research. If the offeror cannot obtain this certification by the time of proposal submission they must include an explanation in their proposal. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(End of provision)

Alternate I (DEC 2015).

As prescribed in HHSAR 370.303(a), the Contracting Officer shall substitute the following paragraph (g) for paragraph (g) of the basic clause.

(g) The offeror's proposal shall document that it has an approved or active FWA from OHRP, related to the designated IRB reviewing and overseeing the research. When possible the offeror shall also certify the IRB has reviewed and approved the research. If the offeror cannot make this certification at the time of proposal submission, its proposal must include an explanation. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

If the offeror does not have an active FWA from OHRP, the offeror shall take all necessary steps to obtain an FWA prior to the deadline for proposal submission. If the offeror cannot obtain an FWA before the proposal submission date, the proposal shall indicate the steps/actions the offeror will take to obtain OHRP approval within *(Contracting Officer must insert a time period in which the FWA must be obtained).* Upon obtaining FWA approval, submit the approval notice to the Contracting Officer.

352.270-4b Protection of Human Subjects.

As prescribed in HHSAR 370.304(a), the Contracting Officer shall insert the following clause:

Protection of Human Subjects (DEC 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 Web site 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)

352.270-5a Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

As prescribed in HHSAR 370.403(a), the Contracting Officer shall insert the following provision:

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (DEC 2015)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for

projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (Email: *olaw@od.nih.gov*; Phone: 301-496-7163).

(End of provision)

352.270-5b Care of Live Vertebrate Animals.

As prescribed in HHSAR 370.404, the Contracting Officer shall insert the following clause:

Care of Live Vertebrate Animals (DEC 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 of 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)

352.270-6 Restriction on Use of Human Subjects.

As prescribed in HHSAR 370-304(b), the Contracting Officer shall insert the following clause:

Restriction on Use of Human Subjects (DEC 2015)

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) registered with OHRP. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

(End of clause)

352.270-7-352.270-8 [Reserved]

352.270-9 Non-Discrimination for Conscience.

As prescribed in HHSAR 370.701, the Contracting Officer shall insert the following provision:

Non-Discrimination for Conscience (DEC 2015)

(a) Section 301(d) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, as amended, provides that an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961, under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, or under any amendment to the foregoing Acts for HIV/AIDS prevention, treatment, or care—

(1) Shall not be required, as a condition of receiving such assistance, to—

(i) Endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

(ii) Endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.

(2) Shall not be discriminated against under the provisions of law in subparagraph (a) for refusing to meet any requirement described in paragraph (a)(1) in this solicitation.

(b) Accordingly, an offeror who believes this solicitation contains work requirements requiring it endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS, or endorse, utilize, make referral to, become integrated with, or otherwise participate in a program or activity to which it has a religious or moral objection, shall identify those work requirements it excluded in its technical proposal.

(c) The Government acknowledges that an offeror has specific rights, as cited in paragraph (b), to exclude certain work requirements in this solicitation from its proposal. However, the Government reserves the right to not make an award to an offeror whose proposal does not comply with the

salient work requirements of the solicitation. Any exercise of that Government right will be made by the Head of the Contracting Activity.

(End of provision)

352.270-10 Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.

As prescribed in HHSAR 370.303(d), the Contracting Officer shall insert the following provision:

Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (DEC 2015)

(a) All Offerors proposing research expected to involve human subjects shall comply with the regulations set forth in 45 CFR part 46, and with the provisions at HHSAR 352.270-4a.

(b) The Offeror shall have an acceptable Assurance of Compliance on file with the Office for Human Research Protections (OHRP), whenever it submits a proposal to the FDA for research expected to involve human subjects. Direct questions regarding Federal-wide Assurance to OHRP. The Offeror's proposal shall include a copy of the acceptable Assurance of Compliance.

(c) After the contract has been awarded, the Contractor shall take the following actions:

(1) The Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance, hereafter referred to as “the local IRB,” shall review the proposed research protocol. A letter from the local IRB stating that the proposed research protocol has been reviewed and approved, and thus adequately protects the rights and welfare of human subjects involved, or a letter stating that the proposed research is exempt under 45 CFR 46.101(b) shall be submitted to the Contracting Officer.

(2) Upon award, the successful Offeror, hereafter “the Contractor,” shall submit its proposed research protocol to the FDA's Research Involving Human Subjects Committee (RIHSC). The RIHSC or its designee will review and approve the research protocol to assure it adequately protects the rights and welfare of human subjects involved. The RIHSC or designee will also determine whether the proposed research is exempt under 45 CFR 46.101(b). The Contractor shall submit, to the Contracting Officer of record, a copy of the RIHSC's or its designee's letter stating that it reviewed and approved the proposed research protocol.

(d) The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects until RIHSC or its designee reviews and approves its research. The Contractor may begin other limited aspects of contract performance prior to receiving RIHSC's or designee's approval of the proposed research protocol. Research involving human subjects may commence immediately upon the Contractor's receipt of RIHSC's or designee's approval; however, the Contractor shall submit a copy of RIHSC's or its designee's approval to the Contracting Officer within three business days of its receipt.

(e) A Contractor's failure to obtain RIHSC's or its designee's approval of its proposed research may result in termination of its contract. However, failure to obtain RIHSC's or its designee's approval during initial review will not automatically result in termination of the contract. Instead, the Contractor may correct any deficiencies identified during the initial RIHSC or designee review and resubmit the proposed research protocol to RIHSC or its designee for a second review. The

Contractor is encouraged to solicit the RIHSC's or its designee's input during the resubmission process.

(f) The Contractor shall seek RIHSC's or its designee's and local IRB review and approval whenever making modifications, amendments or other changes to the research protocol. Such modifications, amendments and changes include, but are not limited to changes in investigators, informed consent forms, and recruitment advertisements. The Contractor may institute changes immediately after receiving both the local IRB and RIHSC or its designee approval (except when necessary to eliminate apparent immediate hazards to the subject); however, the Contractor shall submit a copy of the letter evidencing RIHSC's or its designee's approval of the proposed changes to the Contracting Officer within three business days of its receipt.

(End of provision)

352.270-11 Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.

As prescribed in HHSAR 370.304(c), the Contracting Officer shall insert the following clause:

Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (DEC 2015)

(a) The Contractor agrees to protect the rights and welfare of human subjects involved in research under this contract by complying with 45 CFR part 46 and the clause at HHSAR 352.270-4b.

(b) Initial proof of compliance with 45 CFR part 46 shall consist of:

(1) A copy of a current Federal-wide Assurance on file with OHRP. The copy of a current Federal-wide Assurance shall be included with the Contractor's proposal;

(2) A letter from the Contractor's local IRB (the Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance) stating that it has reviewed and approved the proposed research protocol. The letter from the local IRB shall be submitted to the Contracting Office; and

(3) A copy of a letter from the RIHSC stating that it or its designee has reviewed and approved the proposed research protocol. This shall be submitted to the Contracting Officer within three business days of its issuance.

The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects under this contract, until RIHSC has reviewed and approved its research. The Contractor may commence other limited aspects of contract performance prior to receiving RIHSC or its designee approval of its proposed research protocol. Research involving human subjects may commence immediately upon the Contractor's receipt of RIHSC or its designee approval; however, the Contractor shall submit a copy of RIHSC's or its designee's letter of approval to the Contracting Officer within three business days of its receipt.

Failure to obtain RIHSC or its designee approval of proposed research protocols may result in the termination of this contract.

(c) The Contractor further agrees that:

(1) The Contractor will provide a letter from RIHSC, at least annually, stating that RIHSC or its designee has reviewed and approved the research protocols for research performed under this contract. This shall be submitted to the Contracting Officer for inclusion in the contract file.

(2) The Contractor will submit all proposed modifications and amendments to research protocols for research performed under this contract to RIHSC for review and approval. Modifications and amendments include, but are not limited, to changes to consent forms and advertising materials, and the addition or deletion of investigators. Changes may be instituted immediately after the Contractor has received both the local IRB and RIHSC or its designee approval (except when necessary to eliminate apparent immediate hazards to the subject); however the Contractor shall submit a copy of the letter evidencing RIHSC's or its designee's approval of the proposed changes to the Contracting Officer within three business days of its receipt.

(End of clause)

352.270-12 Needle Exchange.

As prescribed in HHSAR 370.304(d), the Contracting Officer shall insert the following clause:

Needle Exchange (DEC 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)

352.270-13 Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.

As prescribed in HHSAR 370.304(e), the Contracting Officer shall insert the following clause:

Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research (DEC 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)