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(b) When the term “order” is specified in a prescription for a solicitation provision or order clause, it means an order that exceeds the micro-purchase threshold but which does not exceed the simplified acquisition threshold, except those bilateral awards specified in (a)(2) above.

(c) If a clause is included in the master instrument (e.g., in an IDIQ contract or a BPA), it is not necessary to also include the clause in a task order or delivery order thereunder.

(d) 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

352.201-70 Paperwork Reduction Act.

As prescribed in 301.106(b), the Contracting Officer shall insert the following clause:

PAPERWORK REDUCTION ACT (JANUARY 2006)

(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 Technical 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 OMB Clearance is received. Once OMB Clearance is received from the Contracting Officer’s Technical Representative, the Contracting Officer shall provide 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)

352.202-1 Definitions.

As prescribed in FAR 2.201, the Contracting Officer shall insert the clause in FAR 32.202-1, Definitions, as revised by 302.201:

DEFINITIONS (JANUARY 2006)

(a) In accordance with 32.202-1(a)(1), substitute the following as paragraph (a):

“(a) The term “Secretary” or “Head of the Agency” (also called “Agency Head”) means the Secretary, Deputy Secretary, or Assistant Secretary, Administrator or Commissioner of the Department of Health and Human Services; and the term “his/her duly authorized representative” means any person, persons, or board authorized to act for the Secretary.”

(b) In accordance with 32.202-1(a)(1), add the following paragraph (h):

“(h) The term “Contracting Officer’s Technical Representative” means the person who monitors the technical aspects of contract performance. The Contracting Officer’s Technical Representative is not authorized to issue any instructions or directions which cause any increase or decrease in the Statement of Work/Performance Work Statement/Specifications which would result in the increase or decrease in the price of this contract, or changes in the delivery schedule or period of performance of this contract. If applicable, the Contracting Officer’s Technical Representative is not authorized to receive or act upon any notification or revised cost estimate provided by the Contractor in accordance with the Limitation of Cost or Limitation of Funds clauses of this contract.”

352.203-70 Anti-lobbying.

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

ANTI-LOBBYING (JANUARY 2006)

Pursuant to the current HHS annual appropriations act, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for (i) publicity or propaganda purposes; (ii) the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television or video presentation designed to support or defeat legislation
The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement: "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with nonconforming statement(s).

352.215-70 Late proposals and revisions.

As prescribed in 315.209, the Contracting Officer shall insert the following provision:

LATE PROPOSALS AND REVISIONS (JANUARY 2006)

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 the best value 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.

As prescribed in 316.307(j), the Contracting Officer shall insert the following clause:

ADDITIONAL COST PRINCIPLES (JANUARY 2006)

(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 direct 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 paragraphs, 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 319.270–1(a), the Contracting Officer shall insert the following provision:

MENTOR-PROTÉGÉ PROGRAM (JANUARY 2010)

(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 http://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 developmental assistance.) 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 businesses; and (iii) have a Mentor-Protégé agreement approved by HHS’ OSDBU and (End of provision)

352.219–71 Mentor-protégé program reporting requirements.

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

CONTRACTOR COOPERATION IN EQUAL EMPLOYMENT OPPORTUNITY INVESTIGATIONS (JANUARY 2010)

(a) In addition to complying with the clause in 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, e-mail address, and telephone number, if that employee has been identified as a witness in an EEO complaint or investigation.

(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)

[74 FR 62398, Nov. 27, 2009, as amended at 75 FR 21511, Apr. 26, 2010]

352.223–70 Safety and health.

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

SAFETY AND HEALTH (JANUARY 2006)

(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.

(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)


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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 stop work order shall be subject to a claim for extension of time 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)

352.224–70 Privacy Act.

As prescribed in 324.103(b)(2), the Contracting Officer shall insert the following clause:

PRIVACY ACT (JANUARY 2006)

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 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 subcontractor agreements entered into by the Contractor 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)


PATENT RIGHTS—EXCEPTIONAL CIRCUMSTANCES (SEP 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 device 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 DÉC, 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. (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) (previously incorporated herein by reference). If greater rights 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 conditions 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)
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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 permit the investigation 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 or other suitable educational programs, on the importance of reporting inventions or other suitable educational programs, on the importance of reporting inventions or other suitable educational programs, on the importance of reporting inventions or other suitable educational programs, on the importance of reporting inventions or other suitable educational programs, on the importance of reporting inventions or other suitable educational programs, on the importance of reporting inventions or other suitable educational programs, on the importance of reporting inventions or other suitable educational programs, on the importance of reporting inventions or other suitable educational programs, on the importance of reporting inventions or other suitable educational programs, on the importance of reporting inventions.

(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.

(3) Preferences 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, with respect to 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.

(1) 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.

(3) 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]


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)

[79 FR 49018, Aug. 19, 2014]

352.227-14 Rights in Data—Exceptional Circumstances.

As prescribed in 327.409(b)(1), insert the following clause with any appropriate alternates:

RIGHTS IN DATA—EXCEPTIONAL CIRCUMSTANCES (SEP 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—(1) Means (A) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allows 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.

(2) 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.

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) Substitute 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.

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 under this paragraph, 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 copyrighted license as set forth in paragraph (c)(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—

(i) As prohibited by Federal law or regulation (e.g., export control or national security laws or regulations);

(ii) As expressly set forth in this contract; or

(iii) 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. (1) 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;
(i) 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 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.

(ii) 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 not 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)(i) 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.

Omitted or incorrect markings. (1) Data delivered to the Government without any restrictive markings shall be deemed to have been furnished with unlimited rights. The Government is not liable for the disclosure, use, or reproduction of such data.

(2) If the unmarked data has not been disclosed without restriction outside the Government, the Contractor may request, within 6 months (or a longer time approved by the Contracting Officer in writing for good cause shown) after delivery of the data, permission to have authorized notices placed on the data at the Contractor’s expense. The Contracting Officer may agree to do so if the Contractor—

(i) Identifies the data to which the omitted notice is to be applied;

(ii) Demonstrates that the omission of the notice was inadvertent;

(iii) Establishes that the proposed notice is authorized; and

(iv) Acknowledges that the Government has no liability for the disclosure, use, or reproduction of any data made prior to the addition of the notice or resulting from the omission of the notice.

(3) If data has been marked with an incorrect notice, the Contracting Officer may—

(i) Permit correction of the notice at the Contractor’s expense if the Contractor identifies the data and demonstrates that the correct notice is authorized; or

(ii) Correct any incorrect notices.

(g) Protection of limited rights data and restricted computer software.

(1) The Contractor may withhold from delivery qualifying limited rights data or restricted computer software that are not data identified in paragraphs (b)(1)(i) through (iii) of this clause. As a condition to this withholding, the Contractor shall—

(i) Identify the data being withheld; and

(ii) Furnish form, fit, and function data instead.

(2) Limited rights data that are formatted as a computer database for delivery to the Government shall be treated as limited rights data and not restricted computer software.

(3) [Reserved]

(h) Subcontracting. The Contractor shall obtain from its subcontractors all data and rights therein necessary to fulfill the Contractor’s obligations to the Government under this contract. If a subcontractor refuses to accept terms affording the Government those rights, the Contractor shall promptly notify the Contracting Officer of the refusal and shall not proceed with the subcontract award without authorization in writing from the Contracting Officer.

(i) Relationship to patents or other rights. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government.

(End of clause)

Alternate I (SEPT 2014). As prescribed in 327.409, substitute the following definition for “limited rights data” in paragraph (a) of the basic clause:

[Definition]

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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 (SEP 2014). As prescribed in 327.409, insert the following paragraph (g)(3) in the basic clause:

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

LIMITED RIGHTS NOTICE (SEP 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 (SEP 2014). As prescribed in 327.409, insert the following paragraph (g)(4) in the basic clause:

(g)(4) Notwithstanding paragraph (g)(3) 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 (SEP 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 (SEP 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
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352.227-70 Publications and publicity.

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

PUBLICATIONS AND PUBLICITY (JANUARY 2006)

(a) Unless otherwise specified in this contract, the Government encourages the Contractor to publish the results of its work under this contract. A copy of each article the Contractor submits for publication shall be promptly sent to the Contracting Officer’s Technical Representative. The Contractor shall also inform the Contracting Officer’s Technical Representative when the article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized by the Contracting Officer’s Technical Representative, the Contractor shall not display the HHS logo on any publications.

(End of clause)

352.228-7 Insurance—liability to third persons.

As prescribed in 328.311–2, the Contracting Officer shall insert the following clause and either Alternate I or II, as appropriate:

INSURANCE—LIABILITY TO THIRD PERSONS (DECEMBER 1991)

(a)(1) Except as provided in paragraph (a)(2) immediately following, or in paragraph (h) of this clause [if the clause has a paragraph (b)], the Contractor shall provide and maintain workers’ compensation, employer’s liability, comprehensive general liability (bodily injury), comprehensive automobile liability (bodily injury and property damage) insurance, and such other insurance as the Contracting Officer may require under this contract.

(2) The Contractor may, with the approval of the Contracting Officer, maintain a self-insurance program; provided that, with respect to workers’ compensation, the Contractor is qualified pursuant to statutory authority.

(3) All insurance required by this paragraph shall be in form and amount and for those periods as the Contracting Officer may require or approve and with insurers approved by the Contracting Officer.

(b) The Contractor agrees to submit for the Contracting Officer’s approval, to the extent and in the manner required by the Contracting Officer, any other insurance that is maintained by the Contractor in connection with performance of this contract and for which the Contractor seeks reimbursement.

(c) Except as provided in paragraph (h) of this clause [if the clause has a paragraph (h)], the Contractor shall be reimbursed—

(1) For that portion of the reasonable cost of insurance allocable to this contract, and required or approved under this clause; and

(2) For certain liabilities (and expenses incidental to such liabilities) to third persons
not compensated by insurance or otherwise within the funds available under the Limitation of Cost or the Limitation of Funds clause of this contract. These liabilities must arise out of the performance of this contract, whether or not caused by the negligence of the Contractor or the Contractor’s agents, servants, or employees, and must be represented by final judgments or settlements approved in writing by the Government. These liabilities are for—

(i) Loss of or damage to property (other than property owned, occupied, or used by the Contractor, rented to the Contractor, or in the care, custody, or control of the Contractor); or

(ii) Death or bodily injury.

(d) The Government’s liability under paragraph (c) of this clause is limited to the amounts reflected in final judgments, or settlements approved in writing by the Government, but in no event to exceed the funds available under the Limitation of Cost or Limitation of Funds clause of this contract. Nothing in this contract shall be construed as implying that, at a later date, the Government will request, or the Congress will appropriate, funds sufficient to meet any deficiencies.

(e) The Government shall not reimburse the Contractor for liabilities (and expenses incidental to such liabilities)—

(1) For which the Contractor is otherwise responsible under the express terms of any clause specified in the Schedule or elsewhere in the contract;

(2) For which the Contractor has failed to insure or to maintain insurance as required by the Contracting Officer; or

(3) That result from willful misconduct or lack of good faith on the part of the Contractor’s directors, officers, managers, superintendents, or other representatives who have supervision or direction of—

(i) All or substantially all of the Contractor’s business;

(ii) All or substantially all of the Contractor’s operations at any one plant or separate location in which this contract is being performed; or

(iii) A separate and complete major industrial operation in connection with the performance of this contract.

(f) The provisions of paragraph (e) of this clause shall not restrict the right of the Contractor to be reimbursed for the cost of insurance maintained by the Contractor in connection with the performance of this contract, other than insurance required in accordance with this clause; provided, that such cost is allowable under the Allowable Cost and Payment clause of this contract.

(g) If any suit or action is filed or any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, and the risk of which is then uninsured or is insured for less than the amount claimed, the Contractor shall—

(1) Immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received;

(2) Authorize Government representatives to collaborate with counsel for the insurance carrier in setting or defending the claim when the amount of the liability claimed exceeds the amount of coverage; and

(3) Authorize Government representatives to settle or defend the claim and to represent the Contractor in or to take charge of any litigation, if required by the Government, when the liability is not insured or covered by the bond. The Contractor may, at its own expense, be associated with the Government representatives in any such claim or litigation.

(End of clause)

Alternate I (APR 1984). If the successful offeror represents in its offer that it is partially immune from tort liability as a State agency, the Contracting Officer shall add the following paragraph (h) to the basic clause:

(h) Notwithstanding paragraphs (a) and (c) of this clause—

(1) The Government does not assume any liability to third persons, nor will the Government reimburse the Contractor for its liability to third persons, with respect to loss due to death, bodily injury, or damage to property resulting in any way from the performance of this contract or any subcontract under this contract; and

(2) The Contractor need not provide or maintain insurance coverage as required by paragraph (a) of this clause; provided, that the Contractor may obtain any insurance coverage deemed necessary, subject to approval by the Contracting Officer as to form, amount, and duration. The Contractor shall be reimbursed for the cost of such insurance and, to the extent provided in paragraph (c) of this clause, for liabilities to third persons for which the Contractor has obtained insurance coverage as provided in this paragraph, but for which such coverage is insufficient in amount.

(End of clause)

Alternate II (APR 1984). If the successful offeror represents in its offer that it is totally immune from tort liability as a State agency, the Contracting Officer shall substitute the following paragraphs (a) and (b) for paragraphs (a) and (b) of the basic clause:
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(a) The Government does not assume any liability to third persons, nor will the Government reimburse the Contractor for its liability to third persons, with respect to loss due to death, bodily injury, or damage to property resulting in any way from the performance of this contract or any subcontract under this contract.

(b) If any suit or action is filed, or if any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, the Contractor shall immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received by the Contractor. The Contractor shall, if Government requires, authorize Government representatives to settle or defend the claim and to represent the Contractor in or take charge of any litigation. The Contractor may, at its own expense, be associated with the Government representatives in any such claims or litigation.

(End of clause)

352.231–70 Salary rate limitation.

As prescribed in 331.101–70, the Contracting Officer shall insert the following clause:

**SALARY RATE LIMITATION (JANUARY 2010)**

(a) Pursuant to the current and applicable prior HHS appropriations acts, 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 I in effect on the date an expense is incurred.

(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 [F&A] costs).

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with Federal funds.

(c) The salary rate limitation also applies to individuals under subcontracts. 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 in effect when the expense is incurred regardless of the rate initially used to establish contract or order funding.

(d) See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

(End of clause)

352.231–71 Pricing of adjustments.

As prescribed in 331.102–70, the Contracting Officer shall insert the following clause:

**PRICING OF ADJUSTMENTS (JANUARY 2001)**

When costs are a factor in determination of a contract price adjustment pursuant to the “Changes” clause or any provision of this contract, the applicable cost principles and procedures set forth below shall form the basis for determining such costs:

<table>
<thead>
<tr>
<th>Paragraph</th>
<th>Principles</th>
<th>Types of organizations</th>
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</thead>
<tbody>
<tr>
<td>(a)</td>
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<td>Commercial.</td>
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<tr>
<td>(b)</td>
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<td>(c)</td>
<td>Subpart 31.6 of the Federal Acquisition Regulation</td>
<td>State, local, and Federally recognized Indian Tribal governments.</td>
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<tr>
<td>(d)</td>
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<td>Hospitals (performing research and development contracts only).</td>
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<tr>
<td>(e)</td>
<td>Subpart 31.7 of the Federal Acquisition Regulation</td>
<td>Other nonprofit organizations.</td>
</tr>
</tbody>
</table>
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Choice of law (overseas).

As prescribed in 332.215–70(a), the Contracting Officer shall insert the following clause:

**Choice of Law (Overseas) (January 2010)**

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 Civilian Board of Contract Appeals and 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)

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Litigation and claims.

As prescribed in 332.215–70(b), the Contracting Officer shall insert the following clause:

**Litigation and Claims (January 2006)**

(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 papers 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.

(End of clause)

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Notice of earned value management system—pre-award Integrated Baseline Review.

As prescribed in 334.203–70(a), the Contracting Officer shall insert the following provision:

**Notice of Earned Value Management System—Pre-Award Integrated Baseline Review (October 2008)**

The offeror shall provide documentation that its proposed Earned Value Management System (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (current version at time of solicitation).

(a) If the offeror proposes to use a system that currently does not meet the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the guidelines:

(i) The plan shall—

(ii) Distinguish between the offeror’s existing management system and modifications proposed to meet the guidelines;

(iii) Describe the management system and its application in terms of the EVMS guidelines;

(iv) Describe the proposed procedure for application of the EVMS requirements to subcontractors;

(v) Provide documentation describing the process and results, including Government participation if applicable, of any third-party evaluation or self-evaluation of the
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system’s compliance with the EVMS guidelines; and

(vi) Provide a schedule of events leading up to formal validation and Government acceptance of the offeror’s EVMS, if the value of the offeror’s proposal, including options, is $25 million or more.

(2) The offeror shall provide information and assistance, as required by the Contracting Officer, to support review of the plan.

(3) The Contracting Officer will review the offeror’s EVMS implementation plan prior to contract award.

(4) The offeror’s EVMS plan must provide milestones indicating when the offeror anticipates that the EVMS will be compliant with the ANSI/EIA Standard-748 guidelines.

(b) The offeror shall identify in its offer the subcontractors, or subcontracted effort if subcontractors have not been identified, to which the requirements of EVMS will be applied. Prior to contract award, the offeror and HHS shall agree on the subcontractors, or subcontracted effort, subject to the EVMS requirement.

(c) HHS will conduct an Integrated Baseline Review prior to contract award. The offeror shall be compensated as set forth elsewhere in this solicitation for its preparation for and participation in the IBR.

(End of provision)

352.234–2 Notice of earned value management system—post-award Integrated Baseline Review.

As prescribed in 334.203–70(b), the Contracting Officer shall insert the following provision:

NOTICE OF EARNED VALUE MANAGEMENT SYSTEM—POST-AWARD INTEGRATED BASELINE REVIEW (OCTOBER 2008)

(a) The offeror shall provide documentation that its proposed Earned Value Management System (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (current version in effect at time of solicitation).

(b) If the offeror proposes to use a system that currently does not meet the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the guidelines.

(1) The plan shall—

(i) Describe the EVMS the offeror intends to use in performance of the contract;

(ii) Distinguish between the offeror’s existing management system and modifications proposed to meet the guidelines;

(iii) Describe the management system and its application in terms of the EVMS guidelines;

(iv) Describe the proposed procedure for application of the EVMS requirements to subcontractors;

(v) Provide documentation describing the process and results, including Government participation if applicable, of any third-party evaluation or self-evaluation of the system’s compliance with the EVMS guidelines; and

(vi) Provide a schedule of events leading up to formal validation and Government acceptance of the offeror’s EVMS, if the value of the offeror’s proposal, including options, is $25 million or more.

(2) The offeror shall provide information and assistance, as required by the Contracting Officer, to support review of the plan.

(3) The Contracting Officer will review the offeror’s EVMS implementation plan prior to contract award.

(4) The offeror’s EVMS plan must provide milestones indicating when the offeror anticipates that the EVMS system will be compliant with the ANSI/EIA Standard-748 guidelines.

(c) The offeror shall identify in its offer the subcontractors, or subcontracted effort if subcontractors have not been identified, to which the requirements of EVMS will be applied. Prior to contract award, the offeror and HHS shall agree on the subcontractors, or subcontracted effort, subject to the EVMS requirement.

(d) HHS will conduct an Integrated Baseline Review after contract award.

(End of provision)

352.234–3 Full earned value management system.

As prescribed in 334.203–70(c), the Contracting Officer shall insert the following clause:

FULL EARNED VALUE MANAGEMENT SYSTEM (OCTOBER 2008)

(a) The Contractor shall use an Earned Value Management System (EVMS) that has been validated and accepted by the Cognizant Federal Agency (CFA) as being compliant with the guidelines in ANSI/EIA Standard-748 (current version at time of award) to manage this contract. If the Contractor’s current EVMS has not been validated and accepted by the CFA at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor’s EVM system has not been validated and accepted by the CFA as complying with EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall—
(1) Apply the current system to the contract; and
(2) Take necessary and timely actions to meet the milestones in the Contractor’s EVMS plan approved by the Contracting Officer.
(c) HHS requires the Contractor to obtain validation and acceptance of its EVM system by the CFA during the base period of performance of this contract. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor’s compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action, which may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.
(d) HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than 90 days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.
(e) Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.
(f) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.
(g) The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

(End of clause)

Alternate I (October 2008) As prescribed in 334.203–70(d), the Contracting Officer shall substitute the following clause:

PARTIAL EARNED VALUE MANAGEMENT SYSTEM (OCTOBER 2008)

(a) The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor’s current EVMS is not compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.
(b) If, at the time of award, the Contractor’s EVMS system is not in compliance with the EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall—
(1) Apply the current system to the contract; and
(2) Take necessary and timely actions to meet the milestones in the Contractor’s EVMS plan approved by the Contracting Officer.
(c) HHS will not formally validate or accept the Contractor’s EVMS with respect to this contract. The use of the Contractor’s EVMS for this contract does not imply HHS acceptance of the Contractor’s EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor’s compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

352.234-4 Partial earned value management system.

As prescribed in 334.203–70(d), the Contracting Officer shall insert the following clause:

PARTIAL EARNED VALUE MANAGEMENT SYSTEM (OCTOBER 2008)

(a) The Contractor shall use an Earned Value Management System (EVMS) that has been validated and accepted by the Cognizant Federal Agency (CFA) as being compliant with the schedule-related guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor’s current EVMS has not been validated and accepted by the CFA at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.
(b) If, at the time of award, the Contractor’s EVMS system has not been validated and accepted by the CFA as complying with the
schedule-related EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall:

(1) Apply the current system to the contract; and
(2) Take necessary and timely actions to meet the milestones in the Contractor’s EVMS plan approved by the Contracting Officer.

(c) HHS requires the Contractor to obtain validation and acceptance of the schedule-related portions of its EVM system by the CFA during the base period of performance of this contract. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor’s compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action, which may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

(d) HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than 90 days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.

(e) Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

(f) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.

(g) The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

(End of clause)

Alternate I (October 2008) As prescribed in 334.203-70(d), the Contracting Officer shall substitute the following paragraphs (a), (b), and (c) for paragraphs (a), (b), and (c) of the basic clause and delete paragraph (e) of the basic clause:

(a) The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the schedule-related guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor’s current EVMS is not compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor’s schedule-related EVMS system is not in compliance with the schedule-related EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), or the Contractor does not have an existing schedule control system that is compliant with such guidelines, the Contractor shall:

(1) Apply the current system to the contract; and
(2) Take necessary and timely actions to meet the milestones in the Contractor’s EVMS plan approved by the Contracting Officer.

(c) HHS will not formally validate or accept the Contractor’s schedule-related EVMS with respect to this contract. The use of the Contractor’s EVMS for this contract does not imply HHS acceptance of the Contractor’s EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor’s compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

352.237–70  Pro-Children Act.

As prescribed in 337.103–70(a), the Contracting Officer shall insert the following clause:

PRO-CHILDREN ACT (JANUARY 2006)

(a) Public Law 103–227, Title X, Part C, also known as the Pro-Children Act of 1994 (Act), 20 U.S.C. 7181, 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.
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 subcontractors 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, understand, and comply 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.

(End of clause)


As prescribed in 337.103–70(b), the Contracting Officer shall insert the following clause:

CRIME CONTROL ACT OF 1990—REPORTING OF CHILD ABUSE (JANUARY 2006)

(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, 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, understand, and comply with the provisions of the Act.

(End of clause)
352.239–70 Standard for security configurations.

As prescribed in 339.101(d)(1), the Contracting Officer shall insert the following clause:

STANDARD FOR SECURITY CONFIGURATIONS

(JANUARY 2010)

(a) The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see http://nv.nist.gov/fdcc/index.cfm) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

NOTE: FDCC is applicable to all computing systems using Windows XP™ and Windows Vista™, including desktops and laptops—regardless of function—but not including servers.

(b) The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:


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

(End of clause)

352.239–71 Standard for encryption language.

As prescribed in 339.101(d)(2), the Contracting Officer shall insert the following clause:

STANDARD FOR ENCRYPTION LANGUAGE

(JANUARY 2010)

(a) The Contractor shall use Federal Information Processing Standard (FIPS) 140-2-compliant encryption (Security Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (NOTE: The Government has determined that HHS information under this contract is considered “sensitive” in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2001.)

(b) The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see http://csrc.nist.gov/cryptval/) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer’s Technical Representative.

(c) The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information.

(d) The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).
(e) The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.

(2) Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.

(3) Adopting, and implementing, at a minimum, the policies, procedures, controls, and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.

(c) Contractor security deliverables. In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:

(1) IT Security Plan (IT–SP)—due within 30 days after contract award. The IT–SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT–SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT–SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT–SP applies.

(i) The Contractor's IT–SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107–347), and the following Federal and HHS policies and procedures:


(B) National Institute of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Federal Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT–SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommended Security Controls for Federal Information Systems. The Contractor shall review and update the IT–SP in accordance with NIST SP 800–26, Security Self-Assessment Guide.
for Information Technology Systems and FIPS 200, on an annual basis.

(C) HHS-OCIO Information Systems Security and Privacy Policy.

(i) After resolution of any comments provided by the Government on the draft IT–SP, the Contracting Officer shall accept the IT–SP and incorporate the Contractor’s final version into the contract for Contractor implementation and maintenance. On an annual basis, the Contractor shall provide to the Contracting Officer verification that the IT–SP remains valid.

(2) IT Risk Assessment (IT–RA)—due within 30 days after contract award. The IT–RA shall be consistent, in form and content, with NIST SP 800–30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS–OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT–RA, the Contracting Officer shall accept the IT–RA and incorporate the Contractor’s final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT–RA on an annual basis.

(3) FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)—due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor’s final version into the contract.

(A) IT Security Certification and Accreditation (IT–SC&A)—due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT–SC&A was performed for applicable information systems—see paragraph (a) of this clause. The Contractor shall perform the IT–SC&A in accordance with the HHS Chief Information Security Officer’s Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security Certification and Accreditation of Federal Information Systems; and NIST SP 800-33, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT–SC&A and provide it to the Contracting Officer for review, comment, and acceptance.

(ii) After resolution of any comments provided by the Government on the draft IT–SC&A, the Contracting Officer shall accept the IT–SC&A and incorporate the Contractor’s final version into the contract as a compliance requirement.

(ii) The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT–SC&A remains valid. Evidence of a valid system accreditation includes written results of:

(A) Annual testing of the system contingency plan; and

(B) The performance of security control testing and evaluation.

(d) Personal identity verification. The Contractor shall identify its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COTR evidencing that Contractor employees have completed the required training.

(f) Government access for IT inspection. The Contractor shall afford the Government access to the Contractor’s and subcontractors’ facilities, installations, operations, documentation, databases, and personnel in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

(g) Subcontracts. The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that—

(1) Have physical or electronic access to HHS’ computer systems, networks, or IT infrastructure; or

(2) Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor’s information system.

(h) Contractor employment notice. The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under
this contract, if that employee has, or had, access to HHS information systems or data.

(i) Document information. The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.

(j) Contractor responsibilities upon physical completion of the contract. The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.

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

(End of clause)

[74 FR 62396, Nov. 27, 2009, as amended at 75 FR 21511, Apr. 26, 2010]

352.239–73 Electronic information and technology accessibility.

(a) As prescribed in 339.201–70(a), the Contracting Officer shall insert the following provision:

Electronic and Information Technology Accessibility (January 2010)

(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 Technology Accessibility Standards (36 CFR Part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit—

(1) Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and

(2) Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

(b) As prescribed in 339.201–70(b), the Contracting Officer shall insert the following clause:

Electronic and Information Technology Accessibility (January 2010)

(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

(c) The Section 508 accessibility standards applicable to this solicitation are identified in the statement of Work/Specification/Performance Work Statement. In order to facilitate the Government’s evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 accessibility standard. Instructions for preparing the HHS Section 508 Evaluation Template may be found under Section 508 policy on the HHS Office on Disability Web site (http://www.hhs.gov/od).

(d) Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 accessibility standards conformance, as well as for documenting EIT products or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 accessibility standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government—i.e., after award of a contract/order, that products or services delivered do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the vendor’s Product Assessment Template will be the responsibility of the Contractor and at its expense.

(End of provision)
352.242–70 Key personnel.

As prescribed in 342.302(c)(2), the Contracting Officer shall insert the following clause:

**KEY PERSONNEL (JANUARY 2006)**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

(End of clause)

352.242–71 Tobacco-free facilities.

As prescribed in 342.302(c)(3), the Contracting Officer shall insert the following clause:

**TOBACCO-FREE FACILITIES (JANUARY 2006)**

In accordance with Department of Health and Human Services (HHS) policy, the Contractor and its staff are prohibited from using tobacco products of any kind (e.g., cigarettes, cigars, pipes, and smokeless tobacco) while on any HHS property, including use in personal or company vehicles operated by Contractor employees while on an HHS property. This policy also applies to all subcontracts awarded under the contract or order. The term “HHS properties” includes all properties owned, controlled and/or leased by HHS when totally occupied by HHS, including all indoor and outdoor areas of such properties. Where HHS only partially occupies such properties, it includes all HHS-
occupied interior space. Where HHS leases space in a multi-occupant building or complex, the tobacco-free HHS policy will apply to the maximum area permitted by both law and current lease agreements. The Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understand, and comply with this policy.

(End of clause)


As prescribed in 342.302(c)(4), the Contracting Officer shall insert the following clause:

NATIVE AMERICAN GRAVES PROTECTION AND REPATRIATION ACT (JANUARY 2006)

(a) Public Law 101–601, dated November 16, 1990, also known as the Native American Graves Protection and Repatriation Act (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—

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

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

(iii) 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.

(End of clause)

352.242–74 Final decisions on audit findings.

As prescribed in 342.7003–1(b), the Contracting Officer shall insert the following clause:

FINAL DECISIONS ON AUDIT FINDINGS (APRIL 1984)

For the purpose of issuing final decisions under the Disputes clause of this contract concerning monetary audit findings, the Contracting Officer is the individual authorized to make such decisions.

(End of clause)

352.270–1 Accessibility of meetings, conferences, and seminars to persons with disabilities.

As prescribed in 370.102, the Contracting Officer shall insert the following clause:

ACCESSIBILITY OF MEETINGS, CONFERENCES, AND SEMINARS TO PERSONS WITH DISABILITIES (JANUARY 2001)

The Contractor agrees as follows:

(a) Planning. The Contractor shall develop a plan to assure that any meeting, conference, or seminar held pursuant to this contract will meet or exceed the minimum accessibility standards set forth in 28 CFR 36.101–36.500 and Appendix A: ADA Accessibility Guidelines (ADAAG). The Contractor shall submit the plan to the Contracting Officer’s Technical Representative for approval prior to initiating action. (The Contractor may submit a consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars in lieu of separate plans.)

(b) Facilities. Any facility the Contractor intends to utilize for meetings, conferences, or seminars in performance of this contract shall be in compliance with 28 CFR 36.101–
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36.500 and Appendix A. The Contractor shall determine, by an on-site inspection, that the facility meets these requirements. (1) Parking. Parking shall be in compliance with 228 CFR 36.101–36.500 and Appendix A.

(2) Entrances. Entrances shall be in compliance with 28 CFR 36.101–36.500 and Appendix A.

(3) Meeting Rooms. Meeting rooms, including seating arrangements, shall be in compliance with 28 CFR 36.101–36.500 and Appendix A. In addition, stages, speaker platforms, etc., which are to be used by persons in wheelchairs must be accessible by ramps or lifts. When used, the ramp may not necessarily be independently negotiable if space does not permit. However, the Contracting Officer’s Technical Representative must approve any slope over 1:12, and the Contractor must provide assistance to negotiate access to the stage or platform.

(4) Restrooms. Restrooms shall be in compliance with 28 CFR 36.101–36.500 and Appendix A.

(5) Eating Facilities. Eating facilities in the meeting facility must also comply with 28 CFR 36.101–36.500 and Appendix A.

(6) Overnights. If overnight accommodations are required, the facility providing the overnight accommodations shall also comply with 28 CFR 36.101–36.500 and Appendix A.


(c) Provisions of Services for Attendees with Sensory Impairments.

(1) The Contractor, in planning the meeting, conference, or seminar, shall include in all announcements and other materials pertaining to the meeting, conference, or seminar a notice indicating that services will be made available to persons with sensory impairments attending the meeting, if requested within five (5) days of the date of the meeting, conference, or seminar. The announcement(s) and other material(s) shall indicate that persons with sensory impairments may contact a specific person(s), at a specific address and phone number(s), to make their service requirements known. The phone number(s) shall include a telecommunications device for the deaf (TDD).

(2) The Contractor shall provide, at no additional cost to the individual, those services required by persons with sensory impairments to ensure their complete participation in the meeting, conference, or seminar.

(3) At a minimum, when requested in advance, the Contractor shall provide the following services:

(i) For persons with hearing impairments, qualified interpreters. Also, the meeting rooms shall be adequately illuminated so signing by interpreters can be easily seen.

(ii) For persons with vision impairments, readers and/or cassette materials, as necessary, to enable full participation. Also, meeting rooms shall be adequately illuminated.

(iii) Agenda and other conference material(s) shall be translated into a usable form for persons with sensory impairments. Readers, Braille translations, large print text, and/or tape recordings are all acceptable. These materials shall be available to individuals with sensory impairments upon their arrival.

(4) The Contractor shall make a reasonable effort to ascertain the number of individuals with sensory impairments who plan to attend the meeting, conference, or seminar. However, if the Contractor can determine that there will be no person with sensory impairment in attendance, the provision of those services under paragraph (c) of this clause for the non-represented group, or groups, is not required.

(End of clause)

352.270–2 Indian preference.

As prescribed in 370.202(a), the Contracting Officer shall insert the following clause:

INDIAN PREFERENCE (APRIL 1964)

(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 agrees to give preference in employment and training opportunities under this contract to Indians who are not fully qualified to perform work, regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation. The Contractor 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 statistical records as are necessary to indicate compliance with this paragraph.

(b) In connection with the Indian employment preference requirements of this clause, the Contractor shall provide opportunities for training incident to such employment. Such training shall include on-the-job, classroom, or apprenticeship training which is 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 persons other than Indians 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 to 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 is recognized as eligible for the special programs and services provided by the United States to Indians because of their 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 impose any other sanctions authorized by law or by other provisions of the contract.

352.270-3 Indian preference program.

As prescribed in 370.202(b), the Contracting Officer shall insert the following clause:

INDIAN PREFERENCE PROGRAM (JANUARY 2006)

(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 to be 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 advertisements for employment that Indian applicants will be given preference in employment and training incident to such employment.

3. Not more than 30 calendar days after award of the contract, post a written notice in the Tribal office of any reservations on which or near where the work under this contract is to be performed that sets forth the Contractor’s employment needs and related training opportunities. The notice shall include the approximate numbers and types of employees needed; the approximate dates of employment; the experience or special skills required for employment, if any; 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 work is to be performed to provide assistance to the Contractor in 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 in regard to the posting of notices and requests for Tribal assistance.

(b) Establish and conduct a subcontracting program which gives preference to Indian organizations and Indian-owned economic enterprises as subcontractors and 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
only from Indian organizations or Indian-owned economic enterprises. The Contractor shall request assistance and information on Indian firms qualified as suppliers or subcontractors from the Tribe(s) on or near whose reservation(s) the work under the contract is to be performed. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to be contacted in regard to 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 which facilitate the participation of Indian firms;

(ii) A statement indicating that preference will be given to Indian organizations and Indian-owned economic enterprises 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” as prescribed under the “Indian Preference” clause of this contract;

(iv) A statement to be completed by the bidder or offeror 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, no responsive bid or acceptable proposal is received, the Contractor shall comply with the requirements of paragraph (d) of the “Indian Preference” clause of this contract. If one or more responsive bids or acceptable proposals are received, award shall be made to the low responsible bidder or acceptable offeror if the price is determined to be reasonable. If the low responsive bid or acceptable proposal is determined to be unreasonable as to price, the Contractor shall attempt to negotiate a reasonable price and award a subcontract. If a reasonable price cannot be agreed upon, 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 indicate—

(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 where there are both Indian and non-Indian applicants, and a non-Indian is selected for employment, the reason(s) why the Indian applicant was not selected;

(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 preference was not given to Indian firms as subcontractors or suppliers for each requirement where it was determined by the Contractor that such preference would not be consistent with the efficient performance of the contract; 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 which summarizes the Contractor’s Indian preference program and indicates 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 as may be required by 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. 1611 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 be expected to commute to and from in the course of a work day.

(c) Nothing in the requirements of this clause shall be interpreted to 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 impose any other sanctions authorized by law or by other provisions of the contract.

(End of clause)

352.270-4 Protection of human subjects.

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

NOTICE TO OFFERORS OF REQUIREMENTS OF 45 CFR PART 46, PROTECTION OF HUMAN SUBJECTS (JANUARY 2006)

(a) Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects 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 through intervention or interaction with the individual, or identifiable private information. 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. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1–6) are exempt from coverage.

(d) Inappropriate designations of the non-involvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Government’s Project Officer will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, the Project Officer will consult with OHRP.

(e) In accordance with 45 CFR Part 46, offerors being considered for award shall file with OHRP an acceptable Assurance of Compliance 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.

(f) Offerors may consult with OHRP for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

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

PROTECTION OF HUMAN SUBJECTS (JANUARY 2006)

(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 Assurance of Compliance 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. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. 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 imputing liability on the part of the Government for the acts of the Contractor or its employees.
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(c) If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and 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, and the Contractor’s name may be removed from the list of those contractors with approved Human Subject Assurances.

(End of clause)

352.270–5 Care of laboratory animals.

(a) As prescribed in 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 (JANUARY 2006)

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 award may be made to an applicant organization, 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, applicant organizations must establish an Institutional Animal Care & Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution’s animal program, facilities and procedures. Applicant organizations are required to provide verification of IACUC approval prior to release of 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 that involve live vertebrate animals that an Assurance and verification of IACUC approval are required.

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, RKLI, Suite 360, MSC 7982 Bethesda, Maryland 20892–7982 (E-mail: olaw@od.nih.gov; Phone: 301–496–7163). (End of provision)

(b) As prescribed in 370.404, the Contracting Officer shall insert the following clause:

CARE OF LIVE VERTEBRATE ANIMALS (OCTOBER 2009)

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture 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.

(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 Sections 2.25 through 2.32. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(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 Sections 2.1–2.11, or from a source that is exempt from licensing under those sections.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with OHRP, OLAW or in part, 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 approved 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 (E-mail: ace@aphis.usda.gov; Web site: (http://www.aphis.usda.gov/animal_welfare).

(End of clause)

352.270-6 Restriction on use of human subjects.

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

**Restriction on use of human subjects (January 2006)**

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) designated under the Contractor’s Federal-wide assurance of compliance. This restriction applies to all collaborators, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

(End of clause)

352.270-7 Conference sponsorship request and conference materials disclaimer.

As prescribed in 370.602, the Contracting Officer shall insert the following clause:

**Conference Sponsorship Request and Conference Materials Disclaimer (January 2010)**

(a) If HHS is not the sole provider of funding under this conference 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/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 by the Contracting Officer’s Technical Representative, the Contractor shall not display the HHS logo on any conference materials.

(End of clause)

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352.270-8 Prostitution and related activities.

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

**Prostitution and related activities (January 2010)**

(a) The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing and contribute to the phenomenon of trafficking in persons.

(b) Neither the Contractor nor any subcontractor(s) shall use Government funds provided under this contract to promote or advocate the legalization or practice of prostitution or sex trafficking. (NOTE: The term “contract” includes “order” wherever it appears in this clause.) The Contractor shall not construe anything in the preceding sentence to preclude providing individuals with palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

(c) The Government does not require the Contractor to endorse or utilize a multisectoral approach to combating HIV/AIDS, or endorse, utilize, or participate in a prevention method or treatment program to which it has a religious or moral objection. Any information the Contractor provides about the use of condoms as part of projects or activities that are funded in connection with this contract shall be medically accurate and shall include the public health benefits and failure rates of such use.

(d) In addition, the Contractor shall have a policy explicitly opposing prostitution and sex trafficking. The preceding sentence shall not apply to any “exempt organizations”
(i.e., the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency), or any other recipient of Leadership Act funds, and Leadership Act funds do not subsidize activities inconsistent with a policy opposing prostitution and sex trafficking. Mere book-trafficking; and

Leadership Act funds, and Leadership Act funds made available through this contract, the Contractor shall certify compliance with this clause.

The Contractor shall provide the three following compliance certifications in a written statement addressed to the Contracting Officer:

(1) Organizational Integrity Certification: “I certify that (insert Contractor’s name), which will be the recipient of Government funds made available through this contract, has objective integrity and independence from any organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking.”

(2) Subcontractor Compliance Certification: “I certify that (insert Contractor’s name) will include the Organizational Integrity certification in any subcontract awarded under this contract and will require such

(d) The following definitions apply for purposes of this clause:

(1) “Commercial sex act” means any sex act on account of which anything of value is given to or received by any person.

(2) “Prostitution” means procuring or providing any commercial sex act.

(3) “Sex trafficking” means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act (22 U.S.C. 7102(9)).

(4) “Specified types of commercial contracts” means contracts awarded for commercial items and services as defined in Federal Acquisition Regulation (FAR) 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding. Notwithstanding the preceding definition of “specified types of commercial contracts,” contracts for the purposes specified in paragraphs (e)(4)(i) through (iii) of this clause, that are awarded to implement HIV/AIDS programs, require that the Contractor have a policy explicitly opposing prostitution and sex trafficking—

(i) Supplies or services provided directly to the final populations receiving such supplies or services in host countries;

(ii) Technical assistance and training furnished directly to host country individuals or entities for the provision of supplies or services to the final populations receiving such supplies and services; or

(iii) The types of services listed in FAR 37.300(b)(1)-(6) that involve giving advice about substantive policies of a recipient, providing managerial or supervisory services; approving financial transactions, personnel actions, etc.).

(f) The Contractor must have and maintain “objective integrity and independence” from any organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking. HHS will consider the Contractor to have objective integrity and independence from such an organization if the—

(1) Organization is a legally separate entity;

(2) Organization receives no transfer of Leadership Act funds, and Leadership Act funds do not subsidize activities inconsistent with a policy opposing prostitution and sex trafficking; and

(3) Contractor is physically and financially separate from the organization. Mere book-keeping separation of Leadership Act funds from other funds is not sufficient. HHS will determine, on a case-by-case basis, and based on the totality of the facts, whether sufficient physical and financial separation exists. The presence or absence of any one factor below will not be determinative. Factors relevant to this determination shall include, but not be limited to, the following:

(i) The existence of separate personnel, management, and governance.

(ii) The existence of separate accounts, accounting records, and timekeeping records.

(iii) The degree of separation from facilities, equipment, and supplies used by the organization to conduct activities inconsistent with a policy opposing prostitution and sex trafficking, and the extent of such activities by the organization.

(iv) The extent to which—

(A) Signs and other forms of identification that distinguish the Contractor from the organization are present, and

(B) Signs and materials that could be associated with the organization or activities inconsistent with a policy opposing prostitution and sex trafficking are absent.

(v) The extent to which the U.S. Government, HHS, and the project name are protected from public association with an organization and its activities that are inconsistent with a policy opposing prostitution and sex trafficking in materials, such as publications, conferences, and press or public statements.

(g) The Contractor shall include, as express terms and conditions, the applicable provisions of this clause in all subcontract solicitations and subcontracts awarded under this contract. The Contractor agrees that HHS may, at any reasonable time, inspect the documents and materials the Contractor maintains or prepares in the usual course of its operations that relate to the Contractor’s compliance with this clause.

(h) As a prerequisite to award and payment of any Government funds under this contract, the Contractor shall certify compliance with this clause for the performance period funded by the contract. The Contractor shall provide the three following compliance certifications in a written statement addressed to the Contracting Officer:

(1) Organizational Integrity Certification: “I certify that (insert Contractor’s name), which will be the recipient of Government funds made available through this contract, has objective integrity and independence from any organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking.”

(2) Subcontractor Compliance Certification: “I certify that (insert Contractor’s name) will include the Organizational Integrity certification in any subcontract awarded under this contract and will require such...
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subcontractor to provide the same certification that the Contractor provided.”

(3) Acknowledgment Certification: “I certify that [insert Contractor’s name] acknowledges that these certifications are a prerequisite to receipt of Government funds in connection with this contract, and that any violation of these certifications by the Contractor or subcontractor(s) at any level shall be grounds for termination of the contract by HHS in accordance with the Federal Acquisition Regulation, Part 49, as well as any other remedies provided by law.”

NOTE: In the case of existing contracts, the Contracting Officer shall add the certification requirements whenever the contract is modified to extend the period of performance or add funds, including any options that may be exercised. In so doing, the Contracting Officer shall delete in paragraph (h) the language “As a prerequisite to award and payment of any Government funds under this contract,” and replace it with: “As a prerequisite to continuation of this contract and payment of any Government funds under it.”

(i) A person(s) authorized to bind the Contractor and any subcontractor(s) shall execute the certifications. The Contractor shall provide its certifications to the Contracting Officer. A subcontractor(s) shall provide its certifications to the Contractor. The Contracting Officer may request that the Contractor provide any subcontractor certifications. In addition, the Contractor and any subcontractors shall provide renewed certifications for any modification that extends the contract period of performance or adds funds to the contract, including any options that may be exercised.

(j) This clause does not affect the applicability of the FAR clause at 52.222–50 entitled, “Combating Trafficking in Persons.”

(End of clause)

[74 FR 62398, Nov. 27, 2009, as amended at 75 FR 21512, Apr. 26, 2010]

352.270–9 Non-discrimination for conscience.

As prescribed in 370.702, the Contracting Officer shall insert the following provision:

NON-DISCRIMINATION FOR CONSCIENCE

(JANUARY 2010)

(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 that would require it to endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS, or to 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 has excluded in its technical proposal.

(c) The Government acknowledges that an offeror has specific rights, as cited in paragraph (b) of this provision, to exclude certain work requirements in this solicitation. 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)

[74 FR 62398, Nov. 27, 2009, as amended at 75 FR 21512, Apr. 26, 2010]

PART 353—FORMS

Subpart 353.3—Illustrations of Forms

Sec. 353.370–674 Form HHS 674, Structured Approach Profit-Fee Objective.


SOURCE: 74 FR 62398, Nov. 27, 2009, unless otherwise noted.