FEDERAL REGISTER

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Part II

Department of Health and Human Services

48 CFR Chapter 3
Health and Human Services Acquisition Regulations; Final Rule
SUMMARY: The Department of Health and Human Services (HHS) is issuing a final rule to amend its Federal Acquisition Regulation (FAR) Supplement, the HHS Acquisition Regulation (HHSAR), to update its regulation to current FAR requirements; to remove information from the HHSAR that consists of material that is internal, administrative, and procedural in nature; to add or revise definitions; to correct certain terminology; and to delete outdated material or material duplicative of the FAR.

DATES: Effective December 18, 2015.

FOR FURTHER INFORMATION CONTACT: Deborah Griffin, Procurement Analyst, Department of Health and Human Services, Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Division of Acquisition, deborah.griffin@hhs.gov.

II. Analysis of Public Comments

HHSAR 315.305, Proposal Evaluation

The respondent states that the coverage in HHSAR 315.305, concerning advisors who are brought in to assist in proposal evaluation has a different set of restrictions and requirements than are found in Part 337, Service Contracting-General, citing those found in FAR 37.203, Policy. The provisions of HHSAR 315.305 specifically address those circumstances when HHS must use a statutorily mandated contractor selection process of Peer Review. As such, the respondent is correct that the primary focus of this HHSAR section deals with potential conflicts which must be avoided in source selection. HHS does not believe that any change to the coverage is necessary. FAR 15.305, Proposal Evaluation, already contains a cross reference to FAR part 37, Service Contracting.
discrimination and then asks that the benefits distributed NOT be subject to this restriction in that certain benefits are, by design, targeted to go to certain defined groups. Another comment also “reiterates that prohibiting contractors from discrimination while delivering taxpayer-funded services in no way violates religious liberty protections.” No change is being made to the coverage. HHS intends to comply with all applicable Federal legislation regarding this subject.

352.270–5a, Notice to Offerors of Requirement for Compliance With the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and 352.270–5b, Care of Live Vertebrate Animals

The respondent asks for further consideration to repeal using animals in research. No change is being made to the coverage. HHS intends to comply with all applicable federal legislation regarding this subject.

352.270–9, Non-Discrimination for Conscience

Several respondents commented on the clause at 352.270–9, Non-Discrimination for Conscience. Most of the comments are identical. Each notes that their concern is with the statute, not the regulation implementing it. They further ask that the law be “robustly operationalized.” HHS intends to enforce section 7631(d) of the Leadership Act. Therefore, no change is being made to the coverage.

352.270–12, Needle Exchange

The respondent commented on the clause at 352.270–12, Needle Exchange, which prevents Federal funds from being used for safe needle exchange. The respondent believes that safe needle exchanges at HHS locations make logical sense. HHS intends to comply with all applicable Federal legislation regarding this subject. Therefore, no change is being made to the coverage.

352.270–13, Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research

Several respondents commented on the clause at 352.270–13, Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research. All but one of the comments were identical. The remaining comment was more expansive. This clause prohibits the use of Federal funds for abortion, creating embryos for the purpose of harvesting cells from them (commonly referred to as “stem cell research”), and the cloning of humans.

The respondents want the rule changed as to abortion to permit abortion in the case of incest, rape, and life endangerment “pursuant to prevailing law.” HHS intends to comply with all applicable Federal legislation regarding this subject. Therefore, no change is being made to the coverage.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This is not a significant regulatory action and, therefore, is not subject to review under section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with 5 U.S.C. 604.

1. Statement of the Need for, and the Objectives of, the Rule

The Department of Health and Human Services (HHS) is revising its Federal Acquisition Regulation (FAR) Supplement, the HHS Acquisition Regulation (HHSAR), to update its regulation to current FAR requirements; to remove information from the HHSAR that consists of material that is internal administrative and procedural in nature; to add or revise definitions; to correct certain terminology; and to delete outdated material or material duplicative of the FAR.

2. Statement of the Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis, a Statement of the Assessment of the Agency of Such Issues, and a Statement of any Changes Made to the Rule as a Result of Such Comments

No issues were raised by the public in response to the initial regulatory flexibility analysis.

3. The Response of the Agency to Any Comments Filed by the Chief Counsel for Advocacy of the Small Business Administration in Response to the Rule, and a Detailed Statement of any Change Made in the Final Rule as a Result of the Comments

No issues were raised by the Chief Counsel for Advocacy of the Small Business Administration in response to the rule.

4. Description of and an Estimate of the Number of Small Entities to Which This Rule Will Apply

HHS awarded approximately 95,836 contract actions in FY 2014; over 44 percent (42,467) of those actions were for small businesses acting as prime contractors; therefore, it is estimated that the rule will apply to over 42,000 small business entities.

5. Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

There are no new reporting, recordkeeping, or other compliance requirements in the final rule. The reporting and recordkeeping requirements are the same as those prior to the proposed rule.

6. Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes

The final rule does not revise or place any new requirements on small business entities. Therefore, this final rule should have no significant economic impact on a substantial number of small business entities.

V. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. Chapter 35) applies. The rule contains information collection requirements. OMB has cleared these information collection requirements under OMB Control Numbers 0990–0430, 0990–0431, 0990–0432, 0990–0433, 0990–0434, and 0990–0436.

List of Subjects in 48 CFR Parts 301 Through 370

Government procurement.

Dated: October 29, 2015.

Angela Billups,
Associate Deputy Assistant Secretary—Acquisition.

For the reasons stated in the preamble, HHS is revising 48 CFR chapter 3 to read as follows:
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Subpart 301.6—Career Development, Contracting Authority, and Responsibilities

301.602 Contracting officers.

301.602–3 Ratification of unauthorized commitments.

(b) Policy. (1) The Government is not bound by agreements with, or contractual commitments made to, prospective contractors by individuals who do not have delegated contracting authority. Unauthorized commitments do not follow the appropriate process for the expenditure of Government funds. Consequently, the Government may not be able to ratify certain actions, putting a contractor at risk for taking direction from a Federal official other than the contracting officer. See FAR 1.602–1. Government employees responsible for unauthorized commitments are subject to disciplinary action. Contractors perform at their own risk when accepting direction from unauthorized officials. Failure to follow statutory and regulatory processes for the expenditure of Government funds is a very serious matter.

(2) The head of the contracting activity (HCA) is the official authorized to ratify an unauthorized commitment. No other re-delegations are authorized.

(c) Limitations. (5) The HCA shall coordinate the request for ratification with the Office of General Counsel, General Law Division and submit a copy to the SPE.

301.603 Selection, appointment, and termination of appointment of contracting officers.

301.603–1 General.

(a) The Agency head has delegated broad authority to the Chief Acquisition Officer, who in turn has further delegated this authority to the SPE. The SPE has further delegated specific acquisition authority to the Operating and Staff Division heads and the HCAs. The HCA (non-delegable) shall select, appoint, and terminate the appointment of contracting officers.

(b) To ensure proper control of redelegated acquisition authorities, HCAs shall maintain a file containing successive delegations of HCA authority through the contracting officer level.

PART 302—DEFINITIONS OF WORDS AND TERMS

Subpart 302.1—Definitions

302.101 Definitions.


Subpart 302.1—Definitions

302.101 Definitions.

(a) Agency head or head of the agency, unless otherwise stated, means the Secretary of Health and Human Services or specified designee.

(b) Contracting Officer’s Representative (COR) is a Federal employee designated in writing by a contracting officer to act as the contracting officer’s representative in monitoring and administering specified aspects of contractor performance after award of a contract or order. In accordance with local procedures, operating divisions (OPDIVs) or staff divisions (STAFFDIVs) may designate CORs for firm fixed-price contracts or orders. CORs’ responsibilities may include verifying that:

(1) The contractor’s performance meets the standards set forth in the contract or order;

(2) The contractor meets the contract or order’s technical requirements by the specified delivery date(s) or within the period of performance; and

(3) The contractor performs within cost ceiling stated in the contract or order. CORs must meet the training and certification requirements specified in 301.604.

(c) Head of the Contracting Activity (HCA) is an official having overall responsibility for managing a contracting activity, i.e., the organization within an OPDIV or STAFFDIV or other HHS organization which has been delegated broad authority regarding the conduct of acquisition functions.

PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

Subpart 303.1—Safeguards

303.101 Standards of conduct.

303.101–3 Agency regulations.

303.104–7 Violations or possible violations of the Procurement Integrity Act.

Subpart 303.2—Contractor Gratuities to Government Personnel

303.203 Reporting suspected violations of the Gratuities clause.

Subpart 303.6—Contracts with Government Employees or Organizations Owned or Controlled by Them

303.602 Exceptions.

Subpart 303.7—Voiding and Rescinding Contracts

303.704 Policy.

Subpart 303.8—Limitation on the Payment of Funds to Influence Federal Transactions

303.808–70 Solicitation provision and contract clause.

Subpart 303.10—Contractor Code of Business Ethics and Conduct

303.1003 Requirements.


Subpart 303.1—Safeguards

303.101 Standards of conduct.

303.101–3 Agency regulations.

(a) The HHS Standards of Conduct are prescribed in 45 CFR part 73.
(ii) Determine the necessary action in accordance with FAR 3.104–7(c) and (d). The HCA shall obtain the approval or concurrence of the ADAS–A before proceeding with an action.

(b) The HCA (non-delegable) shall act with respect to actions taken under the Federal Acquisition Regulation (FAR) clause at 52.203–10, Price or Fee Adjustment for Illegal or Improper Authority.

Subpart 303.2—Contractor Gratuities to Government Personnel

303.203 Reporting suspected violations of the Gratuities clause.

HHS personnel shall report suspected violations of the clause at FAR 52.203–3, Gratuities, to the contracting officer, who will in turn report the matter to the Office of General Counsel (OGC), Ethics Division for disposition.

Subpart 303.6—Contracts with Government Employees or Organizations Owned or Controlled by Them

303.602 Exceptions.

The HCA (non-delegable) is the official authorized to approve an exception to the policy stated in FAR 3.601.

Subpart 303.7—Voiding and Rescinding Contracts

303.704 Policy.

(a) For purposes of supplementing FAR subpart 3.7, the HCA (non-delegable) is the designee. Coordination with the Senior Procurement Executive is required.

Subpart 303.8—Limitation on the Payment of Funds to Influence Federal Transactions

303.808–70 Solicitation provision and contract clause.

The contracting officer shall insert the clause at 352.203–70, Anti-lobbying, in solicitations and contracts that exceed the simplified acquisition threshold.

Subpart 303.10—Contractor Code of Business Ethics and Conduct

303.1003 Requirements.

(b) The contracting officer, when notified of a possible contractor violation, in accordance with FAR 3.1003(b), shall notify the OIG and the HCA.

(c)(2) The contracting officer shall specify the title of HHS’ OIG hotline poster and the Web site where the poster can be obtained in paragraph (b)(3) of the clause at FAR 52.203–14.

PART 304—ADMINISTRATIVE MATTERS

Subpart 304.6—Contract Reporting

304.602 General.

304.604 Responsibilities.

Subpart 304.13—Personal Identity Verification

304.1300 Policy.

Subpart 304.16—Unique Procurement Instrument Identifiers

304.1600 Scope of subpart.

This subpart provides guidance for assigning identification numbers to solicitation or contract actions. The Senior Procurement Executive shall be responsible for establishing a numbering system within the department that conforms to Federal Acquisition Regulation (FAR) subpart 4.16.

Subpart 304.70—[Reserved]

Subpart 304.71—Review and Approval of Proposed Contract Actions

304.7100 Policy.

In accordance with HHS delegated acquisition authority, the FAR, this regulation, internal policies and guidance, the head of the contracting activity (non-delegable) shall establish review and approval procedures for proposed contract actions to ensure that—

(a) Contractual documents are in conformance with law, established policies and procedures, and sound business practices;

(b) Contract actions properly reflect the mutual understanding of the parties; and

(c) The contracting officer is informed of deficiencies and items of questionable acceptability, and takes corrective action.

Subpart 304.72—Affordable Care Act Prevention and Public Health Fund—Reporting Requirements

304.7200 Scope of subpart.

This subpart implements Section 220 of Public Law 112–74, FY 2012 Labor, HHS and Education Appropriations Act, which requires, semi-annual reporting on the use of funds from the Prevention and Public Health Fund (PPHF), Public Law 111–148, sec. 4002. Contractors that receive awards (or modifications to existing awards) with a value of $25,000 or more funded, in whole or in part, from the PPHF, shall report information specified in the clause at 352.204–70, Prevention and Public Health Fund—Reporting Requirements, including, but not limited to—

(a) The dollar amount of contractor invoices;

(b) The supplies delivered and services performed; and

(c) Specific information on subcontracts with a value of $25,000 or more.

304.7201 Procedures.

(a) In any contract action funded in whole or in part by the PPHF, the
contracting officer shall indicate that the contract action is being made under the PPHF, and indicate which products or services are funded under the PPHF. This requirement applies whenever PPHF funds are used, regardless of the contract instrument.

(b) To maximize transparency of PPHF funds that shall be reported by the contractor, the contracting officer shall structure contract awards to allow for separately tracking PPHF funds. For example, the contracting officer may consider awarding dedicated separate contracts when using PPHF funds or establishing contract line item number structures to prevent commingling of PPHF funds with other funds.

(c) Contracting officers shall ensure that the contractor complies with the reporting requirements of 352.204–70. Upon receipt of each report, the contracting officer shall review it for completeness, address any clarity or completeness issues with the contractor, and submit the final approved report in Section 508 compliant format to an Assistant Secretary for Public Affairs point-of-contact for posting on HHS’ PPHF Web site at http://www.hhs.gov/open/prevention/index.html no later than 30 days after the end of the reporting period. If the contractor fails to comply with the reporting requirements, the contracting officer shall exercise appropriate contractual remedies.

(d) The contracting officer shall make the contractor’s failure to comply with the reporting requirements a part of the contractor’s performance information under FAR subpart 42.15.

304.7202 Contract clause.

Insert the clause at 352.204–70, Prevention and Public Health Fund—Reporting Requirements, in all solicitations and contract actions funded in whole or in part with PPHF funds, except classified solicitations and contracts. This includes, but is not limited to, awarding or modifying contracts. This includes, but is not limited to, awarding or modifying contracts. This includes, but is not limited to, awarding or modifying contracts. This includes, but is not limited to, awarding or modifying contracts.

305.7004 Publicizing postaward.

Notices of contract actions exceeding $25,000, funded in whole or in part by the PPHF, shall be identified on HHS’ PPHF Web site at http://www.hhs.gov/open/prevention/index.html no later than 5 days after the contract action occurs.

PART 305—COMPETITION REQUIREMENTS

Subpart 305.2—Full and Open Competition After Exclusion of Sources

(a) The Senior Procurement Executive (SPE) shall prepare the required determination and findings (D&F), see FAR 6.202(b)(1), based on the data provided by program personnel. The appropriate Competition Advocate (CA) (non-delegable) shall sign the D&F, indicating concurrence. The final determination will be made by the SPE.

(b) The contracting officer shall prepare the required determination and findings (D&F), see FAR 6.202(b)(1), based on the data provided by program personnel. The appropriate Competition Advocate (CA) (non-delegable) shall sign the D&F, indicating concurrence. The final determination will be made by the SPE.

Subpart 305.3—Synopses of Contract Awards

305.303 Announcement of contract awards.

(a) Public announcement. The contracting officer shall report awards, not exempt under Federal Acquisition Regulation (FAR) 5.303, to the Office of the Assistant Secretary for Legislation (Congressional Liaison Office). The final determination will be made by the SPE.

Subpart 305.70—Publicizing Requirements Funded From the Affordable Care Act Prevention and Public Health Fund

305.7001 Scope.

Pursuant to appropriations acts, this subpart prescribes requirements for posting presolicitation and award notices for actions funded in whole or in part from the Prevention and Public Health Fund (PPHF). The requirements of this subpart enhance transparency to the public.

305.7002 Applicability.

This subpart applies to actions funded in whole or in part by the PPHF.

305.7003 Publicizing preaward.

Notices of all proposed contract actions, funded in whole or in part by the PPHF, shall be identified on HHS’ Prevention and Public Health Fund Web site at http://www.hhs.gov/open/prevention/index.html no later than 1-day after issuance of the solicitation or other request for proposal or quotation document. When applicable, the notice shall provide a link to the full text; for example, a link to the FedBizOpps notice required by FAR 5.201.
Subpart 306.5—Competition Advocates

306.501 Requirement. The Department Competition Advocate for Health and Human Services is located in the Division of Acquisition.

PART 307—ACQUISITION PLANNING


307.105 Contents of written acquisition plans. Federal Acquisition Regulation 7.105 specifies the content requirements for a written Acquisition Plan (AP). The Department of Health and Human Services requires a written AP for all acquisitions above the simplified acquisition threshold.

PART 308—REQUIRED SOURCES OF SUPPLIES AND SERVICES


Subpart 308.8—Acquisition of Printing and Related Supplies 308.800 Scope of subpart. 308.801 Definitions. 308.802 Policy. 308.803 Solicitation provision and contract clause. Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

308.800 Scope of subpart. This subpart provides the Department of Health and Human Services (HHS) policy for the acquisition of Government printing and related supplies. The HHS Office of the Assistant Secretary for Public Affairs is responsible for the review and clearance of print and electronic publications, printing and related supplies, audiovisual products, and communication service contracts. See FAR 8.802 for exceptions.

308.801 Definitions. The terms “printing” and “duplicating/copying” are defined in the Government Printing and Binding Regulations of the Joint Committee on Printing. The regulations are available at http://www.gpo.gov.

308.802 Policy. In accordance with FAR 8.802(b), the Central Printing and Publications Management Organization at Program Support Center is the HHS designated central printing authority.

308.803 Solicitation provision and contract clause. The contracting officer shall insert the clause at 352.208–70, Printing and Duplication, in all solicitations, contracts, and orders over the simplified acquisition threshold, unless printing or increased duplication is authorized by statute.

PART 309—CONTRACTOR QUALIFICATIONS

Subpart 309.4—Debarment, Suspension, and Ineligibility Sec. 309.403 Definitions. 309.404 System for Award Management (SAM) exclusions. 309.405 Effect of listing (compelling reason determinations). 309.406 Debarment. 309.406–3 Procedures. 309.407 Suspension. 309.407–3 Procedures. 309.470 Reporting of suspected causes for debarment or suspension or the taking of evasive actions. 309.470–1 Situations where reports are required. Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 309.4 Debarment, Suspension, and Ineligibility

309.403 Definitions. The following definition applies to this subpart:

The HHS Suspension and Debarment Official is the Deputy Assistant Secretary (DAS) for the Office of Grants and Acquisition Policy and Accountability (OGAPA).

309.404 System for Award Management (SAM) exclusions.

(c) For actions made by HHS pursuant to FAR 9.406 and 9.407, the Office of Recipient Integrity Coordination shall perform the actions required by FAR 9.404(c).

309.405 Effect of listing (compelling reason determinations).

(a) The head of the contracting activity (HCA) (non-delegable) may, with the written concurrence of the Suspension and Debarment Official, make the determinations referenced in FAR 9.405(a) regarding contracts.

(1) If a contracting officer considers it necessary to award a contract, or consent to a subcontract with a debarred or suspended contractor, the contracting officer shall prepare a determination, including all pertinent documentation, and submit it through appropriate acquisition channels to the HCA. The documentation shall include the date by which approval is required and a compelling reason for the proposed action. Compelling reasons for award of a contract or consent to a subcontract with a debarred or suspended contractor include the following:

(i) Only the cited contractor can provide the property or services, and
(ii) The urgency of the requirement dictates that HHS conduct business with the cited contractor.

(2) If the HCA decides to approve the requested action, the HCA shall request the concurrence of the Suspension and Debarment Official and, if given, shall inform the contracting officer in writing of the determination within the required time period.

309.406 Debarment.

309.406–3 Procedures. Refer all matters appropriate for consideration by an agency Suspension and Debarment Official as soon as practicable to the appropriate Suspension and Debarment Official identified in 309.403. Any person may refer a matter to the Suspension and Debarment Official.

309.407 Suspension.

309.407–3 Procedures. Refer all matters appropriate for consideration by an agency Suspension and Debarment Official as soon as practicable to the appropriate Suspension and Debarment Official identified in 309.403. Any person may refer a matter to the Suspension and Debarment Official.

309.470 Reporting of suspected causes for debarment or suspension or the taking of evasive actions.

309.470–1 Situations where reports are required.

The contracting officer shall report to the HCA and the Associate Deputy
Assistant Secretary—Acquisition

whenever the contracting officer—

(a) Knows or suspects that a contractor is committing or has committed any of the acts described in FAR 9.406–2 or 9.407–2; or

(b) Suspects a contractor is attempting to evade the prohibitions of debarment or suspension imposed under FAR 9.405, or any other comparable regulation, by changes of address, multiple addresses, formation of new companies, or by other devices.

PART 310—MARKET RESEARCH

Sec.
310.001 Policy.


310.001 Policy.

Market research shall be conducted as prescribed in Federal Acquisition Regulation part 10.

PART 311—DEscribing Agency Needs

Subpart 311.70—Section 508 Accessibility Standards

Sec.
311.7000 Defining electronic information technology requirements.

Subpart 311.71—Public Accommodations and Commercial Facilities

311.7100 Policy.

(a) It is HHS policy that all contractors comply with current and any future changes to 28 CFR part 36—Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities. For the purpose of this policy, accessibility is defined as both physical access to public accommodations and commercial facilities, and access to aids and services enabling individuals with sensory disabilities to fully participate in events in public accommodations and commercial facilities.

(b) This policy applies to all contracts requiring contractors to conduct events in public accommodations and commercial facilities open to the public or involving HHS personnel, but not ad hoc meetings necessary or incidental to contract performance.

311.7101 Responsibilities.

The contractor shall submit a plan assuring that any event held will meet or exceed the minimum accessibility standards set forth in 28 CFR part 36. A consolidated or master plan for contracts requiring numerous events in public accommodations and commercial facilities is acceptable.

311.7102 Contract clause.

The contracting officer shall insert the clause at 352.211–1, Public Accommodations and Commercial Facilities, in solicitations, contracts, and orders requiring the contractor to conduct events in accordance with 311.7100(b).

Subpart 311.72—Conference Funding and Sponsorship

311.7200 Policy.

311.7201 Funding and sponsorship.

311.7202 Contract clause.

To ensure that a contractor:

(a) Properly requests approval to designate HHS the conference sponsor, where HHS is not the sole provider of conference funding; and

(b) Includes an appropriate Federal funding disclosure and content disclaimer statement for conference materials, the contracting officer shall include the clause at 352.211–2, Conference Sponsorship Request and Conference Materials Disclaimer, in solicitations, contracts, and orders providing funding which partially or fully supports a conference.

Subpart 311.73—Contractor Collection of Information

311.7300 Policy.

In accordance with the Paperwork Reduction Act (PRA), contractors shall not proceed with collecting information from surveys, questionnaires, or interviews until the COR obtains an Office of Management and Budget clearance and the contracting officer issues written approval to proceed. For any contract involving 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, the contracting officer must comply with the PRA of 1995 (44 U.S.C. 3501 et seq.).

311.7301 Contract clause.

The contracting officer shall insert the clause at 352.211–3, Paperwork Reduction Act, in solicitations, contracts, and orders that require a contractor to collect the same information from 10 or more persons.

PART 312—ACQUISITION OF COMMERCIAL ITEMS

Subpart 312.1—Acquisition of Commercial Items—General

Sec.
312.101 Policy.

Subpart 312.2—Special Requirements for the Acquisition of Commercial Items

312.202(d) Market research and description of agency need.
Subpart 314.1—Opening of Bids and Award of Contract

314.404 Rejection of bids.
314.404-1 Cancellation of invitations after opening.
314.407 Mistakes in bids.
314.407-3 Other mistakes disclosed before award.
314.407-4 Mistakes after award.


Subpart 315.2—Solicitation and Receipt of Proposals and Information

315.204-5 Part IV—Representations and instructions.

(c) Section M, Evaluation factors for award. (1) The requiring activity shall develop technical evaluation factors and submit them to the contracting officer as part of the acquisition plan or other acquisition request documentation for inclusion in a solicitation. The requiring activity shall indicate the relative importance or weight of the evaluation factors based on the requirements of an individual acquisition.

(2) Only a formal amendment to a solicitation can change the evaluation factors.

315.208 Submission, modification, revision, and withdrawal of proposals.

(b) In addition to the provision in Federal Acquisition Regulation (FAR) 52.215–1, Instructions to Offerors—Competitive Acquisition, if the head of the contracting activity (HCA) determines that biomedical or behavioral research and development (R&D) acquisitions are subject to conditions other than those specified in FAR 52.215–1(c)(3), the HCA may authorize for use in competitive solicitations for R&D, the provision at 352.215–70. Late Proposals and Revisions. This is an authorized FAR deviation.

(2) When the provision at 352.215–70 is included in the solicitation and if the HCA intends to consider a proposal or proposals received after the exact time specified for receipt, the contracting officer, with the assistance of cost or technical personnel as appropriate, shall determine in writing that the proposal(s) meets the requirements of the provision at 352.215–70.

Subpart 315.3—Source Selection

315.303–70 Policy.

(a) If an operating division (OPDIV) is required by statute to use peer review for technical review of proposals, the requirements of those statutes, any implementing regulatory requirements, the Federal Advisory Committee Act, and as applicable, any approved Department of Health and Human Services Acquisition Regulation (HHSAR) deviation(s) from this subpart take precedence over the otherwise applicable requirements of this subpart.

(b) The statutes that require such review and implementing regulations are as follows: National Institutes of Health—42 U.S.C. 289a, Peer Review

315.304 Evaluation factors and significant subfactors.

When acquiring electronic and information technology supplies and services (EIT) using negotiated procedures, contracting officers shall comply with Section 508 of the Rehabilitation Act of 1973, as amended.

315.305 Proposal evaluation.

(c) Use of non-Federal evaluators. (1) Except when peer review is required by statute as provided in 315.303–70(a), decisions to disclose proposals to non-Federal evaluators shall be made by the official responsible for appointing Source Selection Evaluation Team members in accordance with OPDIV procedures. The avoidance of organizational and personal conflicts of interest must be taken into consideration when making the decision to use non-Federal evaluators.

(2) When a solicited proposal will be disclosed outside the Government to a contractor or a contractor employee for evaluation purposes, the following or similar conditions shall be part of the written agreement with the contractor prior to disclosure:

CONDITIONS FOR EVALUATING PROPOSALS

The contractor agrees that it and its employees, as well as any subcontractors and their employees (in these conditions, “evaluator”) will use the data (trade secrets, business data, and technical data) contained in the proposal for evaluation purposes only. The foregoing requirement does not apply to data obtained from another source without restriction. Any notice or legend placed on the proposal by either HHS or the offeror shall be applied to any reproduction or abstract provided to the evaluator or made by the evaluator. Upon completion of the evaluation, the evaluator shall return to the Government the furnished copy of the proposal or abstract, and all copies thereof, to the HHS office which initially furnished the proposal for evaluation. The evaluator shall not contact the offeror concerning any aspects of a proposal’s contents.

Subpart 315.4—Contract Pricing

315.404 Proposal analysis.

315.404–2 Information to support proposal analysis.

(a)(2) When some or all information sufficient to determine the reasonableness of the proposed cost or price is already available or can be obtained from the cognizant audit agency, or by other means including data obtained through market research (See FAR part 10 and HHSAR part 310) the contracting officer may request less-than-complete field pricing support (specifying in the request the information needed) or may waive in writing the requirement for audit and field pricing support by documenting the file to indicate what information will be used. When field-pricing support is required, contracting officers shall make the request through the HCA.

Subpart 315.6—Unsolicited Proposals

316.605 Content of unsolicited proposals.

(d) Warranty by offeror. To ensure against contacts between HHS personnel and prospective offerors that would exceed the limits of advance guidance set forth in FAR 15.604 and potentially result in an unfair advantage to an offeror, the prospective offeror of an unsolicited proposal must include the following warranty in any unsolicited proposal. Contracting officers receiving an unsolicited proposal without this warranty shall not process the proposal until the offeror is notified of the missing language and given an opportunity to submit a proper warranty. If no warranty is provided in a reasonable time, the contracting officer shall reject the unsolicited proposal, notify the offeror of the rejection, and document the actions in the file.

UNSOLICITED PROPOSAL WARRANTY BY OFFEROR

This is to warrant that—

(a) This proposal has not been prepared under Government supervision;

(b) The methods and approaches stated in the proposal were developed by this offeror;

(c) Any contact with HHS personnel has been within the limits of appropriate advance guidance set forth in FAR 15.604; and,

(d) No prior commitments were received from HHS personnel regarding acceptance of this proposal.

Date: Organization: Name: Title: (This warranty shall be signed by a responsible management official of the proposing organization who is a person authorized to contractually obligate the organization.)

316.606 Agency procedures.

(a) The HCA is responsible for establishing procedures to comply with FAR 15.606(a).

(b) The HCA or designee shall be the point of contact for coordinating the receipt and processing of unsolicited proposals.

316.606–1 Receipt and initial review.

(d) OPDIVs may consider an unsolicited proposal even though an organization initially submitted it as a grant application. However, OPDIVs shall not award contracts based on unsolicited proposals that have been rejected for grant awards due to lack of scientific merit.

PART 316—TYPES OF CONTRACTS

Subpart 316.3—Cost-Reimbursement Contracts

Sec. 316.307 Contract clauses.

Subpart 316.5—Indefinite-Delivery Contracts

316.505 Ordering.

Subpart 316.6—Time-and-Materials, Labor-Hour, and Letter Contracts

316.603 Letter contracts.

316.603–3 Limitations.


Subpart 316.3—Cost-Reimbursement Contracts

316.307 Contract clauses.

(a)(1) If a contract for research and development is with a hospital (profit or nonprofit), the contracting officer shall modify the “Allowable Cost and Payment” clause at FAR 52.216–7 by deleting from paragraph (a) the words “Federal Acquisition Regulation (FAR) subpart 31.2” and substituting “45 CFR part 75.”

(2) The contracting officer shall also insert the clause at 352.216–70, Additional Cost Principles for Hospitals (Profit or Non-Profit), in solicitations and contracts with a hospital (profit or non-profit) when a cost-reimbursement contract is contemplated.

Subpart 316.5—Indefinite-Delivery Contracts

316.505 Ordering.

(b)(8) The Department of Health and Human Services (HHS) Competition Advocate is the task-order and delivery-
order ombudsman for the department. Ombudsmen for each of the HHS contracting activities shall be designated in writing by the head of the contracting activity. See part 306.

Subpart 316.6—Time-and-Materials, Labor-Hour, and Letter Contracts

316.603 Letter contracts.

316.603–3 Limitations.

An official one level above the contracting officer shall make the written determination, to be included in the contract file, that no other contract type is suitable and to approve all letter contract modifications. No letter contract or modification can exceed the limits prescribed in FAR 16.603–2(c).

PART 317—SPECIAL CONTRACTING METHODS

Subpart 317.1—Multi-Year Contracting

Sec.
317.104 General.
317.105 Policy.
317.105–1 Uses.
317.107 Options.
317.108 Congressional notification.

Subpart 317.2—Options

317.204 Contracts.


Subpart 317.1—Multi-Year Contracting

317.104 General.

(b) The Senior Procurement Executive (SPE) is the agency approving official for determinations under Federal Acquisition Regulation (FAR) 17.104(b).

317.105 Policy.

317.105–1 Uses.

(a) Each head of the contracting activity (HCA) determination to use multi-year contracting, as defined in FAR 17.103, is limited to individual acquisitions where the full estimated cancellation ceiling does not exceed 20 percent of the total contract value over the multi-year term or $12.5 million, whichever is less. Cancellation ceiling provisions shall conform to the requirements of FAR 17.106–1(c). The determination is not delegable and shall address the issues in FAR 17.105–1(a).

(b)(1) SPE approval is required for any—

(i) Individual determination to use multi-year contracting with a cancellation ceiling in excess of the limits in 317.105–1(a); or

(ii) Class determination (see FAR subpart 1.7).

(2) A determination involving a cancellation ceiling in excess of the limits in 317.105–1(a) shall present a well-documented justification for the estimated cancellation ceiling. When the estimated cancellation ceiling exceeds $12.5 million, the determination shall accompany a draft congressional notification letter pursuant to FAR 17.108 and 317.108.

317.107 Options.

When included as part of a multi-year contract, use of options shall not extend the performance of the original requirement beyond 5 years. Options may serve as a means to acquire related services (severable or non-severable) and, upon their exercise, shall receive funding from the then-current fiscal year’s appropriation.

317.108 Congressional notification.

(a) The SPE shall give the approval of the written notification required by FAR 17.108(a). Upon approval of the determination required by 317.105–1(b)(1), the HCA will finalize and sign the congressional notification letter and provide it to the appropriate House and Senate committees.

Subpart 317.2—Options

317.204 Contracts.

(e)(1) Information technology contracts. Notwithstanding FAR 17.204(e), the 5-year limitations apply also to information technology contracts unless a longer period is authorized by statute.

(2) Requests to exceed 5-year limitation. A request to exceed the 5-year limitation specified in FAR 17.204(e) must follow guidance in FAR Part 1.7.

(3) Approval authority. All requests to exceed the 5-year limitations specified in FAR 17.204(e) must be supported with a Determination and Finding and approved by:

(i) The HCA; and

(ii) The HHS SPE.

SUBCHAPTER D—SOCIOECONOMIC PROGRAMS

PART 319—SMALL BUSINESS PROGRAMS

Subpart 319.2—Policies

Sec.
319.201 General policy.
319.201–1 Mentor Protégé Program Solicitation provision and contract clause.


Subpart 319.2—Policies

319.201 General policy.

(d) The functional management responsibilities for the Department of Health and Human Services’ (HHS) small business program are delegated to the Office of Small and Disadvantaged Business Utilization (OSDBU) Director.

(e)(1) The HHS OSDBU Director shall exercise full management authority over the small business program. The small business specialist (SBS) shall review and make recommendations for all acquisitions, unless exempted by statute, that are not being set aside for small business in accordance with Federal Acquisition Regulation (FAR) 19.502. The review must take place prior to issuing the solicitation.

(2) Within the Indian Health Service (IHS), the primary SBSs are responsible for IHS’ overall implementation of the HHS small business program; however, each IHS contracting office will assign a small business technical advisor (SBTA) to perform those functions and responsibilities necessary to implement the small business program. The primary IHS SBS shall assist and provide guidance to respective SBTAs.

319.201–1 Mentor Protégé Program Solicitation provision and contract clause.

(a) The contracting officer shall insert the provision at 352.219–70, Mentor-Protégé Program, in solicitations that include the clause at FAR 52.219–9, Small Business Subcontracting Plan. The provision requires offerors to provide the contracting officer a copy of their HHS Office of OSDBU-approved mentor-protégé agreement in response to a solicitation.

(b) The contracting officer shall insert the clause at 352.219–71, Mentor-Protégé Program Reporting Requirements, in contracts that include the clause at FAR 52.219–9, Small Business Subcontracting Plan, and which are awarded to a contractor with an HHS OSDBU-approved mentor-protégé agreement.

PART 322—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

Subpart 322.8—Equal Employment Opportunity

Sec.
322.810 Solicitation provisions and contract clauses.


Subpart 322.8—Equal Employment Opportunity

322.810 Solicitation provisions and contract clauses.

(b) The contracting officer shall insert the clause at 352.222–70, Contractor Cooperation in Equal Employment Opportunity Investigations, in
solicitations, contracts, and orders that include the clause at FAR 52.222–26, Equal Opportunity.

PART 323—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE

Subpart 323.70—Safety and Health

Sec. 323.7000 Scope of subpart. 323.7001 Policy. 323.7002 Actions required.

Subpart 323.71—Sustainable Acquisition Requirements

323.7100 Policy. 323.7101 Applicability. 323.7102 Procedures.


323.7000 Scope of subpart. This subpart provides procedures for administering safety and health requirements.

323.7001 Policy. The contracting officer shall follow the guidance in this subpart when additional requirements for safety and health are necessary for an acquisition.

323.7002 Actions required.

Contraction activities. The contracting officer shall insert the clause at 352.223–70, Safety and Health, or a clause substantially the same, in solicitations and contracts that involve hazardous materials or hazardous operations for the following types of requirements:

(a) Services or products.
(b) Research, development, or test projects.
(c) Transportation of hazardous materials.
(d) Construction, including construction of facilities on the contractor's premises.

Subpart 323.71—Sustainable Acquisition Requirements

323.7100 Policy. This subpart provides procedures for sustainable acquisitions and use of the following: Designated recycled content; energy efficient, environmentally preferred, Electronic Product Environmental Assessment Tool (EPEAT)-registered, bio-based, water efficient, non-ozone depleting products and services; and alternate fuel vehicles and fuels. The Department of Health and Human Services (HHS) has designated product and service codes for supplies and services having sustainable acquisition attributes. See FAR part 23.

323.7101 Applicability. It is HHS policy to include a solicitation provision and to include an evaluation factor for an offeror's Sustainable Action Plan when acquiring sustainable products and services. This applies only to new contracts and orders above the micro-purchase threshold. Such contracts and orders include, but are not limited to: Office supplies; construction, renovation or repair; building operations and maintenance; landscaping services; pest management; electronic equipment, including leasing; fleet maintenance; janitorial services; laundry services; cafeteria operations; and meetings and conference services. If using a product or service code designated for supplies or services having sustainable acquisition attributes but a review of the requirement determines that no opportunity exists to acquire sustainable acquisition supplies or services, document the determination in the contract file and make note in the solicitation.

323.7102 Procedures. (a) When required by the solicitation, offerors or quoters must include a Sustainable Acquisition Plan in their technical proposal addressing the environmental products and services for delivery under the resulting contract.
(b) The contracting officer shall incorporate the final Sustainable Acquisition Plan into the contract.
(c) The contracting officer shall ensure that sustainability is included as an evaluation factor in all applicable new contracts and orders when the acquisition utilizes a product or service code designated by HHS for supplies or services having sustainable acquisition attributes.

323.7103 Solicitation Provision. The contracting officer shall insert the provision at 352.223–71, Instruction to Offerors—Sustainable Acquisition, in solicitations above the micro-purchase threshold when the acquisition utilizes a product or service code designated by HHS as having sustainable acquisition attributes.

PART 324—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

Subpart 324.1—Protection of Individual Privacy

Sec. 324.103 Procedures for the Privacy Act.

324.104 Restrictions on Contractor Access to Government or Third Party Information.
324.105 Contract clauses.

Subpart 324.70—Health Insurance Portability and Accountability Act of 1996 (HIPAA)

324.7000 Scope of subpart.
324.7001 Policy on Compliance with HIPAA Business Associate Contract Requirements.


Subpart 324.1—Protection of Individual Privacy

324.103 Procedures for the Privacy Act.

(a) The contracting officer shall review all acquisition request documentation to determine whether the requirements of the Privacy Act of 1974 (5 U.S.C. 552a) are applicable. The Privacy Act requirements apply when a contract or order requires the contractor to design, develop, or operate an Privacy Act system of records on individuals to accomplish an agency function. When applicable, the contracting officer shall include the two Privacy Act clauses required by Federal Acquisition Regulation (FAR) 24.104 in the solicitation and contract or order. In addition, the contracting officer shall include the two FAR Privacy Act clauses, and other pertinent information specified in this subpart, in any modification which results in the Privacy Act requirements becoming applicable to a contract or order.

(b) The contracting officer shall ensure that the statement of work or performance work statement (SOW or PWS) specifies the system(s) of records or proposed system(s) of records to the Privacy Act and the implementing regulations are applicable or may be applicable. The contracting officer shall send the contractor a copy of 45 CFR part 5b, which includes the rules of conduct and other Privacy Act requirements.

(c) The contracting officer shall ensure that the contract SOW or PWS specifies for both the Privacy Act and the Federal Records Act the disposition to be made of the system(s) of records upon completion of contract performance. The contract SOW or PWS may require the contractor to destroy the records, remove personal identifiers, or turn the records over to the contracting officer. If there is a legitimate need for a contractor to keep copies of the records after completion of a contract, the contractor must take measures, as approved by the contracting officer, to keep the records
confidential and protect the individuals’ privacy.
(d) For any acquisition subject to Privacy Act requirements, the requiring activity prior to award shall prepare and have published in the Federal Register a “system notice,” describing the Department of Health and Human Services’ (HHS) intent to establish a new system of records on individuals, to make modifications to an existing system, or to disclose information in regard to an existing system. The requiring activity shall attach a copy of the system notice to the acquisition plan or other acquisition request documentation. If a system notice is not attached, the contracting officer shall inquire about its status and shall obtain a copy from the requiring activity for inclusion in the contract file. If a notice for the system of records has not been published in the Federal Register, the contracting officer may proceed with the acquisition of the subcontract until the system notice is published and the contracting officer verifies its publication.

324.104 Restrictions on Contractor Access to Government or Third Party Information.

The contracting officer shall establish the restrictions that govern the contractor employees’ access to Government or third party information in order to protect the information from unauthorized use or disclosure.

324.105 Contract clauses.

(a) The contracting officer shall insert the clause at 352.224–70, Privacy Act, in solicitations, contracts, and orders that require the design, development, or operation of a system of records to notify the contractor that it and its employees are subject to criminal penalties for violations of the Privacy Act (5 U.S.C. 552a(i)) to the same extent as HHS employees. The clause also requires the contractor to ensure each of its employees knows the prescribed rules of conduct in 45 CFR part 5b and that each contractor employee is aware that he or she is subject to criminal penalties for violations of the Privacy Act. These requirements also apply to all subcontracts awarded under the contract or order that require the design, development, or operation of a system of records.

(b) The contracting officer shall insert the clause at 352.224–71, Confidential Information, in solicitations, contracts, and orders that require access to Government or to third party information.

Subpart 324.70—Health Insurance Portability and Accountability Act of 1996

324.7000 Scope of subpart.

All individually identifiable health information that is Protected Health Information (PHI), as defined in 45 CFR 160.103 shall be administered in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) implementing regulations at 45 CFR parts 160 and 164 (the HIPAA Privacy, Security, HHS Breach Notification Rules). The term “HIPAA” is used in this part to refer to title II, subtitle F of the HIPAA statute, at part C of title XI of the Social Security Act, 42 U.S.C. 1320d et seq., section 264 of HIPAA, subtitle D of title XIII of the American Recovery and Reinvestment Act of 2009, and regulations under such provisions.

324.7001 Policy on Compliance with HIPAA business associate contract requirements.

(a) HHS is a HIPAA “covered entity” that is a “hybrid entity” as these terms are defined at sections 160.103 and 164.103 respectively. As such, only the portions of HHS that the Secretary has designated as “health care components,” (HCC) as defined at section 164.103, are subject to HIPAA. HHS HCCs may utilize persons or entities known as “business associates,” as defined at section 160.103. Generally, “business associate” means a “person” as defined by section 160.103 (including contractors, and third-party vendors, etc.) if or when the person or entity:

(1) Creates, receives, maintains, or transmits “protected health information”, as the term is defined at section 160.103, on behalf of an HHS HCC to carry out HIPAA “covered functions” as that term is defined at 164.103; or

(2) Provides certain services to an HHS HCC that involve PHI.

(b) Where the Department as a covered entity is required by 45 CFR 164.502(e)(1) and 164.504(e) and, if applicable, sections 164.308(b)(3) and 164.314(a), to enter into a HIPAA business associate contract, the relevant HCC contracting officer, acting on behalf of the Department, shall ensure that such contract meets the requirements at section 164.304(e)(2) and, if applicable, section 164.314(a)(2).

PART 326—OTHER SOCIOECONOMIC PROGRAMS

Subpart 326.5—Indian Preference in Employment, Training, and Subcontracting Opportunities

Sec. 326.501 Statutory requirements.
326.502 Definitions.
326.503 Compliance enforcement.
326.504 Tribal Preference requirement.
326.505 Applicability.

Subpart 326.6—Acquisitions Under the Buy Indian Act

326.600 Scope of subpart.
326.601 Policy.
326.602 Definitions.
326.603 Requirements.
326.604 Competition.
326.605 Responsibility determinations.

Subpart 326.7—Acquisitions Requiring the Native American Graves Protection and Repatriation Act

326.700 Scope of subpart.
326.701 Applicability.


Subpart 326.5—Indian Preference in Employment, Training, and Subcontracting Opportunities

326.501 Statutory requirements.

Any contract or subcontract pursuant to subchapter II, chapter 14, title 25 of the United States Code, the Act of April 16, 1934 (48 Stat. 596), as amended, or any other Act authorizing Federal contracts with or grants to Indian organizations or for the benefit of Indians, shall, to the greatest extent feasible, comply with section 7(b) of the Indian Self-Determination and Education Assistance Act, Public Law 93–638, 88 Stat. 2205, 25 U.S.C. 450(e)(b) which provides preferences and opportunities for training and employment in connection with the administration of such contracts, and preference in the award of subcontracts in connection with the administration of such contracts to Indian organizations and to Indian-owned economic enterprises as defined in section 1452 of title 25, United States Code.

326.502 Definitions.

For purposes of this subpart, the following definitions shall apply:

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

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

(c) *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).

(d) *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 the ownership shall encompass active operation and control of the enterprise.

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

(f) 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 commute to and from in the course of a work day.

326.503 Compliance enforcement.

The contracting officer shall promptly investigate and resolve written complaints of noncompliance with the requirements of the clauses at 352.226–1, Indian Preference and 352.226–2, Indian Preference Program filed with the contracting activity.

326.504 Tribal preference requirements.

(a) When the contractor will perform work under a contract on an Indian reservation, the contracting officer may supplement the clause at 352.226–2, Indian Preference Program by adding specific Indian preference requirements of the tribe on whose reservation the contractor will work. The contracting activity and the tribe shall jointly develop supplemental requirements for the contract. Supplemental preference requirements shall represent a further implementation of the requirements of section 7(b) of Public Law 93–638 and require the approval of the affected program director and the appropriate legal office, or a regional attorney, before the contracting officer adds them to a solicitation and resultant contract. Any supplemental preference requirements the contracting officer adds to the clause at 352.226–2, Indian Preference Program shall also clearly identify in the solicitation the additional requirements.

(b) Nothing in this part shall preclude tribes from independently developing and enforcing their own tribal preference requirements. Such independently-developed tribal preference requirements shall not, except as provided in paragraph (a) of this section, become a requirement in contracts covered under this subpart, and shall not conflict with any Federal statutory or regulatory requirement concerning the award and administration of contracts.

326.505 Applicability.

The contracting officer shall insert the clause at 352.226–1, Indian Preference, and the clause at 352.226–2, Indian Preference Program, in contracts to implement section 7(b) of Public Law 93–638 for all Department of Health and Human Services (HHS) activities. Contracting activities shall use the clauses as follows, except for those exempted solicitations and contracts issued and or awarded pursuant to Title I of Public Law 93–638 (25 U.S.C. 450 et seq.):

(a) The contracting officer shall insert the clause at 352.226–1, Indian Preference, in solicitations, contracts, and orders when—

(1) The award is (or will be) pursuant to an act specifically authorizing such awards with Indian organizations; or

(2) The work is specifically for the benefit of Indians and is in addition to any incidental benefits which might otherwise accrue to the general public.

(b) The contracting officer shall insert the clause at 352.226–2, Indian Preference Program, in solicitations, contracts, and orders when—

(1) The dollar amount of the acquisition is expected to equal or exceed $650,000 for non-construction work or $1.5 million for construction work;

(2) The solicitation, contract, or order includes the Indian Preference clause; and

(3) The contracting officer makes the determination, prior to solicitation, that performance will take place in whole or in substantial part on or near an Indian reservation(s). In addition, the contracting officer may insert the Indian Preference Program clause in solicitations, contracts, and orders below the $650,000 or $1.5 million level for non-construction or construction contracts, respectively, but which meet the requirements of paragraphs (b)(2) and (3) of this section, and in the opinion of the contracting officer, offer substantial opportunities for Indian employment, training, and subcontracting.

Subpart 326.6—Acquisitions Under the Buy Indian Act

326.600 Scope of subpart.

This subpart sets forth the policy on preferential acquisition from Indians under the negotiation authority of the Buy Indian Act. This subpart applies only to acquisitions made by or on behalf of Indian Health Service (IHS).

326.601 Policy.

(a) IHS shall utilize the negotiation authority of the Buy Indian Act to give preference to Indians whenever authorized and practicable. The Buy Indian Act, 25 U.S.C. 47, prescribes the application of the advertising requirements of 41 U.S.C. 6101 to the acquisition of Indian supplies. As specified in 25 U.S.C. 47, the Buy Indian Act provides that, so far as practicable, the Government shall employ Indian labor and, at the discretion of the Secretary of the Interior, purchase products of Indian industry (including, but not limited to printing, notwithstanding any other law) from the open market.

(b) Due to the transfer of authority from the Department of the Interior to HHS, the Secretary of HHS may use the Buy Indian Act to acquire products of Indian industry in connection with the maintenance and operation of Indian hospital and health facilities, and for the overall conservation of Indian health. This authority is exclusively delegated to IHS and is not available for use by any other HHS component (unless that component makes an acquisition on behalf of IHS). However, the Buy Indian Act itself does not exempt IHS from meeting the statutorily mandated small business goals.

(c) Subsequent legislation, particularly Public Law 94–437 and Public Law 96–537, emphasize using the Buy Indian Act negotiation authority.

326.602 Definitions.

(a) *Buy Indian contract* means any contract involving activities covered by the Buy Indian Act and negotiated under the provisions of 41 U.S.C. 3104 and 25 U.S.C. 47 between an Indian firm and a contracting officer representing IHS.

(b) *Indian* means a member of any tribe, pueblo, band, group, village, or community recognized by the Secretary of the Interior as being Indian or any individual or group of individuals recognized by the Secretary of the Interior or the Secretary of HHS. The
Secretary of HHS in making determinations may take into account the determination of the tribe with which affiliation is claimed.

(c) **Indian firm** means a sole enterprise, partnership, corporation, or other type of business organization owned, controlled, and operated by:

- (1) One or more Indians (including, for the purpose of sections 301 and 302 of Public Law 94–437, former or currently federally recognized Indian tribes in the State of New York); or
- (2) By an Indian firm (as defined in paragraph (1) of this definition); or
- (3) A nonprofit firm organized for the benefit of Indians and controlled by Indians (see 326.601(a)).

(d) **Product of Indian industry** means anything produced by Indians through either physical labor or intellectual effort involving the use and application of their skills. To classify as a product of Indian industry, the total cost of the item's production must equal or exceed 51 percent Indian effort.

### Subpart 326.603 Requirements.

(a) **Indian ownership.** Indian ownership shall constitute at least 51 percent of an Indian firm during the period covered by a Buy Indian contract.

(b) **Joint ventures.** An Indian firm may enter into a joint venture with other entities for specific projects as long as the Indian firm is the managing partner. However, the contracting officer shall approve the joint venture prior to the award of a contract under the Buy Indian Act.

(c) **Bonds.** In the case of contracts for the construction, alteration, or repair of public buildings or public works, the Miller Act (40 U.S.C. 3131 et seq.) and Federal Acquisition Regulation (FAR) part 28 require performance and payment bonds. Bonds are not required in the case of contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe.

However, bonds are required when dealing with private business entities owned by an Indian tribe or members of an Indian tribe. The contracting officer may require bonds of private business entities that are joint ventures with, or subcontractors of, an Indian tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian tribe.

(b) The contracting officer shall make bonds required when a contract under the Buy Indian Act is awarded pursuant to the Buy Indian Act to non-Indian firms. For this purpose, contract work does not include the provision of materials, supplies, or equipment.

(f) **Wage rates.** The contracting officer shall include a determination of the minimum wage rates by the Secretary of Labor as required by the Davis-Bacon Act (40 U.S.C. 276a) in all contracts awarded under the Buy Indian Act for over $2,000 for construction, alteration, or repair, including painting and decorating, of public buildings and public works, except contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe.

The contracting officer shall include the wage rate determination in contracts with private business entities, even when owned by an Indian tribe or a member of an Indian tribe and in connection with joint ventures with, or subcontractors of, an Indian tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian tribe.

### Subpart 326.604 Competition.

(a) Contracts awarded under the Buy Indian Act are subject to competition among Indians or Indian firms to the maximum extent practicable. The contracting officer determines that competition is not practicable, a justification and approval is required in accordance with subpart 306.3.

(b) The contracting officer shall:

- Synopsis and publicize solicitations in the Government point of entry and provide copies of the synopses to the tribal office of the Indian tribal government directly concerned with the proposed acquisition as well as to Indian firms and others having a legitimate interest.
- The synopses shall state that the acquisitions are restricted to Indian firms under the Buy Indian Act.

### Subpart 326.605 Responsibility determinations.

(a) The contracting officer may award a contract under the Buy Indian Act only if it is determined that the contractor will likely perform satisfactorily and properly complete or maintain the contracted project or function.

(b) The contracting officer shall make the written determination specified in paragraph (a) of this section prior to the award of a contract. The determination shall reflect an analysis of FAR 9.104–1 standards.

### Subpart 326.7—Acquisitions Requiring the Native American Graves Protection and Repatriation Act

**326.700 Scope of subpart.**

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

**326.701 Applicability.**

The contracting officer shall insert the clause at 352.226–3, Native American Graves Protection and Repatriation Act, in solicitations, contracts, and orders requiring performance on tribal lands or those for construction projects on Federal or tribal lands.

### Subchapter E—General Contracting Requirements

**PART 327—PATENTS, DATA, AND COPYRIGHTS**

**Subpart 327.3—Patent Rights Under Government Contracts**

Sec. 327.303 Solicitation provision and contract clause.

**Subpart 327.4—Rights in Data and Copyrights**


**Subpart 327.3—Patent Rights Under Government Contracts**

327.303 Solicitation provision and contract clause.

The contracting officer shall insert the clause at 352.227–11, Patent Rights—Exceptional Circumstances and any appropriate alternates in lieu of Federal Acquisition Regulation (FAR) 52.227–11 whenever a Determination of
Exceptional Circumstances (DEC) involving the provision of materials that has been executed in accordance with Agency policy and procedures calls for its use and the clause at 352.227–11, Patent Rights—Exceptional Circumstances, appropriately covers the circumstances. The contracting officer should reference the DEC in the solicitation and shall attach a copy of the executed DEC to the contract.

Subpart 327.4—Rights in Data and Copyrights

327.404–70 Solicitation provision and contract clause.

The contracting officer shall insert the clause at 352.227–70, Publications and Publicity, in solicitations, contracts, and orders that involve requirements which could lead to the contractor’s publishing the results of its work under the contract.

327.409 Solicitation provision and contract clause.

The contracting officer shall insert the clause at 352.227–14, Rights in Data—Exceptional Circumstances, and any appropriate alternates in lieu of the FAR clause at 352.227–14, Rights in Data—General, whenever a DEC executed in accordance with Agency policy and procedures calls for its use. Prior to using this clause, a DEC must be executed in accordance with Agency policy and procedures. The contracting officer should reference the DEC in the solicitation and shall attach a copy of the executed DEC to the contract.

PART 328—[RESERVED]

PART 330—COST ACCOUNTING STANDARDS

Subpart 330.2—CAS Program Requirements

Sec. 330.201 Contract requirements.
330.201–5 Waiver.


Subpart 330.2—CAS Program Requirements

330.201 Contract requirements.
330.201–5 Waiver.

The Senior Procurement Executive (SPE) shall exercise the waiver authority under Federal Acquisition Regulation 30.201–5(a)(2). Operating Divisions and Staff Divisions shall forward waiver requests to the SPE.

PART 331—CONTRACT COST PRINCIPLES AND PROCEDURES

Subpart 331.1—Applicability

Sec. 331.101–70 Salary rate limitation.

Subpart 331.1—Applicability

331.101–70 Salary rate limitation.

(a) Beginning in fiscal year 1990, Congress has stipulated in the Department of Health and Human Services appropriations acts and continuing resolutions that, under applicable contracts, appropriated funds cannot be used to pay the direct salary of an individual above the stipulated rates. The applicable rates for each year are identified at www.opm.gov.

(b) The contracting officer shall insert the clause at 352.231–70, Salary Rate Limitation, in solicitations and contracts when a cost-reimbursement; fixed-price level-of-effort; time-and-materials; or labor-hour contract is contemplated.

PART 332—CONTRACT FINANCING

Subpart 332.4—Advance Payments for Non-Commercial Items

Sec. 332.402 General.
332.407 Interest.

Subpart 332.5—Progress Payments Based on Cost

332.501 General.
332.501–2 Unusual progress payments.
(a) The HCA (non-delegable) shall approve unusual progress payments.

Subpart 332.7—Contract Funding

332.702 Policy.

Departmental employees shall report any suspected violation of the Anti-Deficiency Act (31 U.S.C. 1341, 13 U.S.C. 1342, and 31 U.S.C. 1517) immediately to the Operating Division’s Chief Financial Officer (CFO), who in turn will report the matter to the HHS Deputy CFO.

332.703 Contract funding requirements.

332.703–1 General.

(b) The following requirements govern all solicitations and contracts using incremental funding, as appropriate:

(1) The contracting officer shall consider the estimated total cost of the contract, including all planned increments of performance when determining the requirements that must be met before contract execution (e.g., justification and approvals, clearances, and approvals).

(2) The solicitation and resultant contract shall include a statement of work or performance work statement that describes the total project, covers all proposed increments of performance, and contains a schedule of planned increments of performance. No funding increment may exceed 1 year, and the services rendered during each increment of performance must provide a specific material benefit that can stand alone if the remaining effort is not funded. The resultant contract shall also include the corresponding amount of funds planned for obligation for each increment of performance.

(3) The contracting officer shall request that offerors respond to the solicitation with technical and cost proposals for the entire project, and shall require distinct technical and cost break-outs of the planned increments of performance.

(4) Proposals shall be evaluated and any discussions and negotiations shall be conducted based upon the total project, including all planned increments of performance.

332.703–71 Incrementally funded cost-reimbursement contracts.

Incremental funding may be used in cost-reimbursement contracts for severable services only when all of the following circumstances are present:
(a) Funding of increments after the initial increment of performance is provided from the appropriation account available for obligation at that time;

(b) The project represents a bona fide need of the fiscal year in which the contract is awarded and initially funded (i.e., the initial increment of performance) and is also a bona fide need of each subsequent fiscal year whose appropriation will be used; and

(c) The project’s significance provides reasonable assurance that subsequent year appropriations will be made available to fund the project’s continuation and completion.

332.703–72 Incremental Funding Table.

(a) The contracting officer shall insert substantially the following language in Section B: Supplies or Services and Prices or Costs, Table 1, in all cost-reimbursement contracts for severable services using incremental funding. The language requires the contracting officer to:

(1) Insert the initial funding obligated by the award;

(2) Identify the increment of performance covered by the funding provided; and

(3) Specify the start and end dates for each increment of performance, as required by the “Limitation of Funds” clause at FAR 52.232–22.

(b) Modification of the language is permitted to fit specific circumstances of the contract, including but not limited to language necessary to reflect the specific type of cost reimbursement contract awarded, but the language may not be omitted completely.

Table 1—B. Estimated Cost—Incrementally Funded Contract

(a) The total estimated cost to the Government for full performance of this contract, including all allowable direct and indirect costs, is $____ [insert full amount].

(b) The following represents the schedule* by which the Government expects to allot funds to this contract:

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<tr>
<th>CLIN, task number, or description</th>
<th>Start date of increment of performance</th>
<th>End date of increment of performance</th>
<th>Estimated cost ($) (as appropriate)</th>
<th>Fee ($) (as appropriate)</th>
<th>Estimated cost plus fee ($) (as appropriate)</th>
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* To be inserted after negotiation

(c) Total funds currently obligated and available for payment under this contract are $____ [insert amount funded to date].

(d) The contracting officer may issue unilateral modifications to obligate additional funds to the contract and make related changes to paragraphs (b) and/or (c) above.

(e) Until this contract is fully funded, the requirements of the clause at FAR 52.232–22, Limitation of Funds, shall govern. Once the contract is fully funded, the requirements of the clause at FAR 52.232–20, Limitation of Cost, govern.

332.706 Solicitation provision and contract clauses.

332.706–2 Provision and clauses for limitation of cost or funds.

(b) In addition to the clause at FAR 52.232–22, Limitation of Funds, the contracting officer shall insert the provision at 352.232–70, Incremental Funding, in all solicitations when a cost-reimbursement contract for severable services using incremental funding is contemplated. The provision requires the contracting officer to insert a specific increment of performance that the initial funding is expected to cover.

PART 333—PROTESTS, DISPUTES, AND APPEALS

Subpart 333.1—Protests

Sec. 333.102 General.

333.103 Protests to the agency.

(f)(1) Protests to the contracting officer must be in writing. The contracting officer is authorized to make the determination, using the criteria in Federal Acquisition Regulation 33.104(b), to award a contract notwithstanding the protest after obtaining the concurrence of the contracting activity’s protest control officer and consulting with the appropriate legal office.

Subpart 333.2—Disputes and Appeals

333.203 Applicability.

(c) The Civilian Board of Contract Appeals is the authorized “Board” to hear and determine disputes for the Department.

333.209 Suspected fraudulent claims.

The contracting officer shall submit any instance of a contractor’s suspected fraudulent claim to the Office of Inspector General for investigation.

333.215–70 Contract clauses.

(a) The contracting officer shall insert the clause at 352.233–70, Choice of Law (Overseas), in solicitations and contracts when performance will be outside the United States, its possessions, and Puerto Rico, except as otherwise
provided in a government-to-government agreement.

(b) The contracting officer shall insert the clause at 352.233–71, Litigation and Claims, in solicitations and contracts when a cost-reimbursement, time-and-materials, or labor-hour contract is contemplated (other than a contract for a commercial item).

SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING

PART 334—MAJOR SYSTEM ACQUISITION

Subpart 334.2—Earned Value Management System

Sec. 334.201 Policy.

334.202 Integrated Baseline Reviews (IBRs).


Subpart 334.2—Earned Value Management System

334.201 Policy.

The Department of Health and Human Services applies the earned value management system requirement as follows:

(a) For cost or incentive contracts and subcontracts valued at $20 million or more, the contractor’s earned value management system shall comply with the guidelines in the American National Standards Institute/Electronic Industries Alliance Standard 748, Earned Value Management Systems (ANSI/EIA–748).

(b) For cost or incentive contracts and subcontracts valued at $50 million or more, the contractor shall have an earned value management system requirement as stated in Federal Acquisition Regulation (FAR) 16.303.

(c) If the R&D is expected to be of only minor value to the contractor, and if a statute does not require cost-sharing, it may be appropriate for the contractor to make a contribution in the form of a reduced fee or profit rather than sharing costs of the project. Alternatively, a limitation on indirect cost rates might be appropriate. See FAR 42.707. See also, FAR 16.303.

(d) The contractor’s participation may be considered over the total term of the project, so that a relatively high contribution in 1 year may be offset by a relatively low contribution in another. Care must be exercised that the intent to cost-share in future years does not become illusory. Redetermination of the cost sharing arrangement might be appropriate depending on future circumstances.

(e) A relatively low degree of cost-sharing may be appropriate if an area of R&D requires special stimulus in the national interest.

334.202 Integrated Baseline Reviews (IBRs).

(a) An IBR normally should be conducted as a post-award activity. A pre-award IBR may be conducted only if—

(1) The acquisition plan contains documentation that demonstrates the need and rationale for a pre-award IBR, including an assessment of the impact on the source selection schedule and the expected benefits;

(2) The use of a pre-award IBR is approved in writing by the head of the contracting activity prior to the issuance of the solicitation;

(3) The source selection plan and solicitation specifically addresses how the results of a pre-award IBR will be used during source selection, including any weight to be given to it in source evaluation; and

(4) Specific arrangements are made, and budget authority is provided, to compensate all offerors who prepare for or participate in a pre-award IBR; and the solicitation informs prospective offerors of the means for and conditions of such compensation.

PART 335—RESEARCH AND DEVELOPMENT CONTRACTING

Sec. 335.070 Cost-sharing.

335.070–1 Policy.

335.070–2 Amount of cost-sharing.

When cost-sharing is appropriate, the contracting officer shall use the following guidelines to determine the amount of cost participation by the contractor:

(a) The amount of cost participation depends on the extent to which the R&D effort or results are likely to enhance the contractor’s capability, expertise, or competitive position, and the value of this enhancement to the contractor.

(b) The amount of cost-sharing could reasonably range from as little as one percent or less of the total project cost to more than 50 percent of the total project cost. Ultimately, cost-sharing is a negotiable item. As such, the amount of cost-sharing shall be proportional to the anticipated value of the contractor’s gain.

(c) If the contractor will not acquire title to, or the right to use, inventions, patents, or technical information resulting from the R&D project, it is normally appropriate to obtain less cost-sharing than in cases in which the contractor acquires these rights.

(d) The contractor’s participation may be considered over the total term of the project, so that a relatively high contribution in 1 year may be offset by a relatively low contribution in another. Care must be exercised that the intent to cost-share in future years does not become illusory. Redetermination of the cost sharing arrangement might be appropriate depending on future circumstances.

(e) A relatively low degree of cost-sharing may be appropriate if an area of R&D requires special stimulus in the national interest.

335.070–3 Method of cost-sharing.

Cost-sharing on individual contracts may be accomplished either by a contribution of part or all of one or more elements of allowable cost of the work being performed or by any fixed amount or stated percentage of the total allowable...
costs of the project. Contractors shall not charge costs contributed to the
Government under any other instrument (e.g., grant or contract), including
allocations to other instruments as part of any independent R&D program.

335.071 [Reserved]

335.072 Key personnel.
If the contracting officer determines that the personnel to be assigned to
perform effort on an R&D contract are critical to the success of the R&D effort,
or were a critical factor in the award of the contract, then the contracting officer
should consider using the key personnel clause at 352.237–75, Key Personnel.

PART 336—CONSTRUCTION AND
ARCHITECT-ENGINEER CONTRACTS

Subpart 336.1—General
Sec.
336.104 Policy.

Subpart 336.5—Contract Clause
336.570 Contract clause.

Authority: 5 U.S.C. 301; 40 U.S.C.
121(c)(2).

Subpart 336.1—General
336.104 Policy.
Contracting officers shall follow the policies described in Federal Acquisition Regulation 36.104 and the
guidance promulgated by the Department of Health and Human Services Facilities Management.

Subpart 336.5—Contract Clause
336.570 Contract clause.

(a) The contracting officer shall insert the clause at 352.236–70, Design-Build
Contracts, in all solicitations and contracts for all design-build
requirements.

(b) The contracting officer shall use Alternate I to the clause at 352.236–70,
Design-Build Contracts, in all solicitations and contracts for
construction when Fast-Track procedures are being used.

(c) Due to the importance of maintaining consistency in the contractor’s personnel during design-
build construction, the contracting officer should consider including the clause at 352.237–75, Key Personnel.

PART 337—SERVICE
CONTRACTING—GENERAL

Subpart 337.1—Service Contracts—General
Sec.
337.103 Contracting officer responsibility.

Authority: 5 U.S.C. 301; 40 U.S.C.
121(c)(2).

Subpart 337.1—Service Contracts—General
337.103 Contracting officer responsibility.

(d)(1) The contracting officer shall insert the clause at 352.237–70, Pro-
Children Act, in solicitations, contracts, and
orders that involve:

(i) Kindergarten, elementary, or

(ii) Health or daycare services that are

provided to children under the age of 18

on a routine or regular basis pursuant to

the Pro-Children Act of 1994 (20 U.S.C.

6081–6084).

(2) The contracting officer shall insert the clause at 352.237–71, Crime Control
Act—Reporting of Child Abuse, in
solicitations, contracts, and orders that
require performance on Federal land or
in a federally operated (or contracted)
facility and involve the professions/activities performed by persons
specified in the Crime Control Act of
1990 (42 U.S.C. 13031) including, but
not limited to, teachers, social workers,
physicians, nurses, dentists, health care
practitioners, optometrists, psychologists,
emergency medical technicians, alcohol or drug treatment personnel,
child care workers and
administrators, emergency medical
technicians and ambulance drivers.

(3) The contracting officer shall insert the clause at 352.237–72, Crime Control
Act—Requirement for Background
Checks, in solicitations, contracts, and
orders that involve providing child care
services to children under the age of 18,
including social services, health and
mental health care, child- (day) care,
education (whether or not directly
involved in teaching), and rehabilitative
programs covered under the Crime

(4) Contracting officers supporting the
Indian Health Service shall insert the
clause at 352.237–73, Indian Child
Protection and Family Violence Act in
all solicitations, contracts, and orders
when performance of the contract may
involve regular contact with or control
over Indian children. The required
declaration shall also be included in
Section J of the solicitation and contract.

(e) The contracting officer shall insert the
clause at 352.237–74, Non-
Discrimination in Service Delivery, in
solicitations, contracts, and orders to
deliver services under HHS’ programs
directly to the public.

(f) The contracting officer shall insert the
clause at 352.237–75, Key
Personnel, in solicitations and contracts
when the contracting officer will require
the contractor to designate contractor
key personnel.

PART 339—ACQUISITION OF
INFORMATION TECHNOLOGY

Subpart 339.1—General
Sec.
339.101 Policy.

Subpart 339.2—Electronic and Information
Technology
339.201 Applicability.
339.203–70 Contract clauses for electronic
and information technology (EIT)
acquisitions.
339.204 Exceptions.
339.204–1 Approval of exceptions.
339.205 Section 508 accessibility standards
for contracts.

Authority: 5 U.S.C. 301; 40 U.S.C.
121(c)(2).

Subpart 339.1—General
339.101 Policy.
In addition to the regulatory guidance in Federal Acquisition Regulation part 39, contracting officers shall collaborate with the requiring activity to ensure information technology (IT) acquisitions for supplies, services, and systems meet the requirements established by the Department of Health and Human Services (HHS).

Subpart 339.2—Electronic and
Information Technology
339.203 Applicability.
(a) Electronic and information technology (EIT) supplies and services must comply with Section 508 of the
Rehabilitation Act (the 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 (Access Board) Electronic and Information
Accessibility Standards (36 CFR part
1194). Requirements must consult with their Section 508 Official or
designee to determine if the contractor should be responsible for compliance with EIT accessibility standards which apply to Web site content and communications material.

(1) When conducting a procurement and employing the best value
continuum, the solicitation shall include a separate technical evaluation factor developed by the contracting officer, requiring activity, and the
Operating Division (OPDIV) Section 508
Official or designee.

(2) At a minimum, solicitations for supplies and services shall require the
submission of a Section 508 Product Assessment Template (See http://
www.hhs.gov/web/508 for the template).

Solicitations for services shall include any other pertinent information that the
contracting officer deems necessary to evaluate the offeror’s ability to meet the
applicable Section 508 accessibility standards.

(3) The HHS Operating Division or Staff Division (OPDIV or STAFFDIV) Section 508 Official or designee is responsible for providing technical assistance in development of Section 508 evaluation factors.

(4) Before conducting negotiations or making an award, the contracting officer shall provide a summary of the Source Selection Evaluation Team’s (SSET) assessment of offeror responses to the solicitation’s Section 508 evaluation factor. This summary shall be submitted for review by the Section 508 Official or designee. The Section 508 Official or designee shall indicate approval or disapproval of the SSET assessment. The contracting officer shall coordinate the resolution of any issues raised by the Section 508 Official or designee with the chair of the SSET or requiring activity representative, as appropriate. The acquisition process shall not proceed until the Section 508 Official or designee approves the SSET assessment. The contracting officer shall include the assessment in the official contract file. See 339.204–1 regarding processing exception determination requests.

(b) When acquiring commercial items, if no commercially available supplies or services meet all of the applicable Section 508 accessibility standards, OPDIVs or STAFFDIVs shall, under the direction and approval of the Section 508 Official or designee, acquire the supplies and services that best meet the applicable Section 508 accessibility standards. Process exception determinations for EIT supplies and services not meeting applicable Section 508 accessibility standards in accordance with 339.204–1.

339.203–70 Contract clauses for electronic and information technology (EIT) acquisitions.

(a) The contracting officer shall insert the provision at 352.239–73, Electronic and Information Technology Accessibility Notice, in all solicitations.

(b) The contracting officer shall insert the clause at 352.239–74, Electronic and Information Technology Accessibility, in all contracts and orders.

339.204 Exceptions.

339.204–1 Approval of exceptions.

(a) Procedures to document exception and determination requests are set by the OPDIV Section 508 Official.

(b) In the development of an acquisition plan (AP) or other acquisition request document, the contracting officer shall ensure that all Section 508 exception determination requests for applicable EIT requirements are:

(1) Documented and certified in accordance with the requirements of the HHS Section 508 policy;

(2) Signed by the requestor in the requiring activity;

(3) Certified and approved by the OPDIV Section 508 Official or designee; and

(4) Included in the AP or other acquisition request document provided by the requiring activity to the contracting office.

(c) For instances with an existing technical evaluation and no organization’s proposed supplies or services meet all of the Section 508 accessibility standards; in order to proceed with the acquisition, the requiring activity shall provide an exception determination request along with the technical evaluation team’s assessment of the Section 508 evaluation factor to the designated Section 508 Official or designee for review and approval or disapproval. The contracting officer shall include the Section 508 Official’s or designee’s approval or disapproval of the exception determination request in the official contract file and reference it, as appropriate, in all source selection documents. For further information, see HHS Section 508 Policy on http://www.hhs.gov/web/508.

339.205 Section 508 accessibility standards for contracts.

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794(d)), as amended by the Workforce Investment Act of 1998 (Section 508), specifies the applicable accessibility standards for all new solicitations and new or existing contracts or orders, regardless of EIT dollar amount.

(b) The requiring activity shall consult with the OPDIV or STAFFDIV Section 508 Official or designee, as necessary, to determine the applicability of Section 508, identify applicable Section 508 accessibility standards, and resolve any related issues before forwarding a request to the contracting or procurement office for the acquisition of EIT supplies and services—including Web site content and communications material for which the contractor must meet EIT accessibility standards.

(c) Based on those discussions, the requiring activity shall provide a statement in the AP (or other acquisition request document) for Section 508 applicability. See 307.105. If Section 508 applies to an acquisition, include the provision at 352.239–73, Electronic and Information Technology and Accessibility Notice, language in a separate, clearly designated, section of the statement of work or performance work statement, along with any additional information applicable to the acquisition’s Section 508 accessibility standards (e.g., the list of applicable accessibility standards of the Access Board EIT Accessibility Standards (36 CFR part 1194)). If an AP does not address Section 508 applicability and it appears an acquisition involves Section 508, or if the discussion of Section 508 applicability to the acquisition is inadequate or incomplete, the contracting officer shall request the requiring activity modify the AP accordingly.

(d) Items provided incidental to contract administration are not subject to this section.

(e) The OPDIV Section 508 Official or designee may, at his or her discretion, require review and approval of solicitations and contracts for EIT supplies and services.

SUBCHAPTER G—CONTRACT MANAGEMENT

PART 342—CONTRACT ADMINISTRATION

Subpart 342.7—Indirect Cost Rates

Sec. 342.705 Final indirect cost rates.


Subpart 342.7—Indirect Cost Rates

342.705 Final indirect cost rates.

Contract actions for which the Department of Health and Human Services is the cognizant Federal agency:

(a) The Financial Management Services, Division of Cost Allocation, Program Support Center, shall establish facilities and administration costs, also known as indirect cost rates, research patient care rates, and, as necessary, fringe benefits, computer, and other special costing rates for use in contracts awarded to State and local governments, colleges and universities, hospitals, and other nonprofit organizations.

(b) The National Institute of Health, Division of Financial Advisory Services, shall establish indirect cost rates and similar rates for use in contracts awarded to for profit organizations.
352.270–5a Notice to Offerors of Technology Accessibility Notice.

352.270–4b Protection of Human Subjects.

352.270–3 [Reserved]

352.270–1 [Reserved]

352.239–74 Electronic Information and Delivery.

352.239–73 Electronic Information and Family Violence Act.

352.237–74 Crime Control Act—

352.237–70 Pro-Children Act.

352.236–70 Design-Build Contracts.

352.233–70 Choice of Law (Overseas).

352.227–70 Publications and Publicity.

352.227–14 Rights in Data—Exceptional Circumstances.


352.226–1 Indian Preference.

352.225–70 Confidential Information.

352.223–71 Instructions to Offerors—Safety and Health.

352.222–70 Contractor Cooperation in Equal Employment Opportunity Investigations.

352.221–1 Public Accommodations and Commercial Facilities.


352.211–3 Paperwork Reduction Act.

352.211–50 Application of provisions and clauses.

352.203–70 Anti-Lobbying.

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

352.208–70 Printing and Duplication.

352.201–70 Late Proposals and Revisions.

352.200 Scope of subpart.

352.101–70 Application of provisions and clauses.

352.100 Scope of subpart.

Section 508 compliant format to the Contracting Officer, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

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

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

As prescribed in HHSAR 304.7201, insert the following clause:

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

(a) Pursuant to public law this contract requires the contractor to provide products or services or both that are funded from the Prevention and Public Health Fund (PPHF).

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

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

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

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

3. The Contractor shall provide the following information in an electronic and Section 508 compliant format to the Contracting Officer:

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

2. The amount of PPHF funds invoiced by the Contractor for the reporting period and the cumulative amount invoiced for the contract or order.
(3) A list of all significant services performed or supplies delivered, including construction, for which the contractor invoiced in the reporting period.

(4) Program or project title, if any.

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

(i) Name and address of the subcontractor.

(ii) Amount of the subcontract award.

(iii) Date of the subcontract award.

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

(End of clause)

352.208–70 Printing and Duplication.

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

Printing and Duplication (DEC 2015)

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

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

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

(End of clause)


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

Conference Sponsorship Request and Conference Materials Disclaimer (DEC 2015)

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

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

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

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

(End of clause)

352.211–3 Paperwork Reduction Act.

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

Paperwork Reduction Act (DEC 2015)

(a) This contract involves a requirement to collect or record information calling for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties; therefore, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single time) may be used without the Office of Management and Budget (OMB) first providing clearance. Contractors and the Contracting Officer’s Representative shall be guided by the provisions of 5 CFR part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

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

(End of provision)

352.215–70 Late Proposals and Revisions.

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

Late Proposals and Revisions (DEC 2015) Deviation

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

(End of provision)

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

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

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

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

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

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

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

(b) R&D costs.
(1) R&D is research and development conducted by an organization which is not sponsored by Federal or non-Federal contracts, grants, or other agreements.
(2) R&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 R&D, including its proportionate share of indirect costs, is unallowable.

(End of provision)

352.219–71 Mentor-Protégé Program Reporting Requirements.

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

Mentor-Protégé Program Reporting Requirements (January 2010)

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

(End of clause)

352.222–70 Contractor Cooperation in Equal Employment Opportunity Investigations (DEC 2015)

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

Contractor Cooperation in Equal Employment Opportunity Investigations (DEC 2015)

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

(1) Complaint means a formal or informal complaint that has been lodged with Agency management, Agency EEO officials, the Equal Employment Opportunity Commission (EEOC), or a court of competent jurisdiction. (2) Contractor employee means all current Contractor employees who work or worked under this contract. The term also includes current employees of subcontractors who work or worked under this contract. In the case of Contractor and subcontractor employees, who worked under this contract, but who are no longer employed by the Contractor or subcontractor, or who have been assigned to another entity within the Contractor’s or subcontractor’s organization, the Contractor shall provide the Agency with that employee’s last known mailing address, email address, and telephone number, if that employee has been identified as a witness in an EEO complaint or investigation.

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

(i) Formal and informal interviews by EEO counselors or other Agency officials processing EEO complaints;
(ii) Formal or informal interviews by EEO investigators charged with investigating complaints of unlawful discrimination filed by Federal employees;
(iii) Reviewing and signing appropriate affidavits or direct the Contractor to summarize statements provided by such Contractor employees during the course of EEO investigations;
(iv) Producing documents requested by EEO counselors, EEO investigators, Agency employees, or the EEOC in connection with a pending EEO complaint; and
(v) Preparing for and providing testimony in depositions or in hearings before the MSPB, EEOC and U.S. District Court.

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

(End of clause)

352.223–70 Safety and Health.

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

Safety and Health (DEC 2015)

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

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


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

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


(b) Further, the Contractor shall take or cause to be taken additional safety measures.
as the Contracting Officer, in conjunction with the Contracting Officer’s Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required to identify any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable “Changes” clause set forth in this contract.

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

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

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

(End of clause)

352.223–71 Instructions to Offerors—Sustainable Acquisition.

As prescribed in HHSAR 324.105(b), the Contracting Officer shall insert the following provision:

Instructions to Offerors—Sustainable Acquisition (DEC 2015)

Offerors must include a Sustainable Acquisition Plan in their technical proposals.

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

(End of provision)

352.224–70 Privacy Act.

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

Privacy Act (DEC 2015)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations.

The term system of records means a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)).

The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in 45 CFR part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)). The contractor work statement:

(a) Identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and

(b) Specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

352.224–71 Confidential Information.

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

Confidential Information (DEC 2015)

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

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

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

(1) Written advance notice of at least 45 days shall be provided to the Contracting Officer of the Contractor’s intent to release findings of studies or research, to which an agency response may be appropriate to protect the public interest or that of the agency.

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

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

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

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

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

352.226–1 Indian Preference.

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

Indian Preference (DEC 2015)

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

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

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

(d) If no Indian organizations or Indian-owned economic enterprises are available under reasonable terms and conditions, including price, for awarding of subcontracts in connection with the work performed under this contract, the Contractor agrees to comply with the provisions of this contract involving utilization of small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; women-owned small businesses; or small disadvantaged businesses.

(e) As used in this clause,

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

(2) Indian tribe means an Indian tribe, pueblo, band, nation, or other organized group or community, including Alaska Native villages or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 668; 43 U.S.C. 1601) which the United States recognizes as eligible for the special programs and services provided to Indians because of its status as Indians.

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

(4) Indian-owned economic enterprise means any Indian-owned commercial, industrial, or agricultural 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.

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

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

(End of clause)

352.226-2 Indian Preference Program.

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

**Indian Preference Program (DEC 2015)**

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

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

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

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

(4) The Contractor shall comply with the provisions of paragraph (d) of the “Indian Preference” clause of this contract. If the Contractor receives one or more responsive bids or conforming proposals, the Contractor shall award the contract to the low, responsive, responsible bidder or conforming offer from a responsible offeror if the price is reasonable.

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

(i) The number and type of employment opportunities which exist under this contract;

(ii) The number of Indian organizations and Indian-owned economic enterprises for subcontracting opportunities which exist under this contract;

(iii) The number of Indian firms to submit bids or proposals which were not acceptable or reasonable. The Contractor shall maintain a record of the reasons why the Contractor did not select the Indian applicant;

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

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

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

(6) Submit to the Contracting Officer for approval a quarterly report summarizing the Contractor’s Indian preference program and opportunities shall provide an equitable opportunity for Indian firms to submit bids or proposals by including—

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

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

(End of clause)
indicating the number and types of available positions filled by Indians and non-Indians, and the dollar amounts of all subcontracts awarded to Indian organizations and Indian-owned economic enterprises, and to all other firms.

(7) Maintain records pursuant to this clause and keep them available for review by the Government for one year after final payment under this contract, or for such longer period in accordance with requirements of any other clause of this contract or any 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 groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601 et seq.)

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

(c) Nothing in the requirements of this clause shall preclude Indian tribes from independently developing and enforcing their own Indian preference requirements.

(4) Indian Preference means a preference concerning the purposes, and to permit other U.S. nonprofit research including for educational purposes, and to permit other U.S. nonprofit organizations qualified under a state nonprofit organization statute.

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

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

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

(2) Notify the Contracting Officer of the discovery;

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

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


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

Patent Rights—Exceptional Circumstances (SEPT 2014)

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

(a) Definitions. As used in this clause—

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

(2) Class 1 Subject Invention means a Subject Invention described and defined in the DEC.

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

Class 3 Subject Invention means a Subject Invention for which the Contracting Officer, at his or her discretion, determines that the requirements of this clause are warranted.

DEC means the Determination of Exceptional Circumstances issued by the Contracting Officer.

(3) Dependent contractor means a contractor, subcontractor (at all tiers) Subject Inventions to the provider of the Material.

(4) Independent contractor means a contractor, subcontractor (at all tiers) Subject Inventions to the provider of the Material.

(5) Independent contractor (at all tiers) Subject Inventions to the provider of the Material means any invention of the Contractor that is entering into this contract.

(6) Independent contractor (at all tiers) Subject Inventions to the provider of the Material and other party designated by the Agency means any invention of the Contractor or any other party designated by the Agency.

(7) Independent contractor (at all tiers) Subject Inventions to the provider of the Material or other party designated by the Agency means any invention of the Contractor or any other party designated by the Agency.

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

(8) 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 to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

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

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

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

(a) Allocation of principal rights.

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

(2) Allocation of Subject Invention rights.

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

(B) Reserved.

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

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

Patent Right—Ownership by the Contractor (March 1990) (previously incorporated herein by reference).
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 DETR of the acceptance of any manuscript describing the invention for publication or 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 the responsibility of 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 may 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)(i) of FAR clause 52.227–13. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

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

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

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

(2) In subcontracts, at any tier, the Agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer on any third party assignee the right to use the Government's patent and the right to accept licenses on the Government's behalf.

(g) Preference for United States industry 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 concerning 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.

(h) March-in rights in the event greater rights are granted to the Contractor. Notwithstanding any other provision of this clause, the Contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses 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.
Contractor acknowledges that, with respect to any Subject Invention in which it has acquired ownership through the exercise of the rights specified in paragraph (b)(3) of this clause, the Agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of Agency in effect on the date of contract award.

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

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

(2) Share royalties collected on a Subject Invention with the Government, face page of the patent disclosures, confirmatory licenses to the Contractor, and negotiate changes to its licensing policies, procedures, or practices that will more effectively implement the requirements of paragraph (i)(4) of this clause.

(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) Determine that fees 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 other plan or proposal for marketing that is submitted; 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 (ii)(4) of this clause.

(j) Communications. All invention disclosures and requests for greater rights shall be sent to the Agency Contracting Officer, as the contracting officer’s representative. 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)(i)(a) is as follows:

[Insert description of license to Class 2 inventions]

(End of clause)

352.227-14 Rights in Data—Exceptional Circumstances.

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

Rights in Data—Exceptional Circumstances (SEPT 2014)

(a) Definitions. As used in this clause—

Definitions may be added or modified in paragraph (a) as applicable.

Computer database or database means a collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

Computer software—(i) Means (A) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the medium in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and (B) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

(ii) Does not include computer databases or computer software documentation.

Computer software documentation means owner’s manuals, user’s manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

Data means recorded information, regardless of form or the media on which it is stored, that is included in or is incidental to the administration of Subject Inventions for the support of scientific or technical nature that is included in computer databases (See 41 U.S.C. 403(8)).

Unlimited rights means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

(b) Allocation of rights. (1) Except as provided in paragraph (c) of this clause, the Government shall have unlimited rights in—

(i) Data first produced in the performance of this contract;

(ii) Form, fit, and function data delivered under this contract;

(iii) Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, maintenance of the rights of the Government in original and repair of items, components, or processes delivered or furnished for use under this contract; and

(iv) All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph (g) of this clause.

(2) The Contractor shall have the right to—

(i) Assert copyright in data first produced in the performance of this contract to the extent provided in paragraph (c)(1) of this clause;

(ii) Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, unless provided otherwise in paragraph (d) of this clause;

(iii) Substantiate the use of, add, or correct limited rights, restricted rights, or copyright notices and to take other appropriate action, in accordance with paragraphs (e) and (f) of this clause; and

(iv) Protect from unauthorized disclosure and use those data that are limited rights data or restricted computer software to the extent provided in paragraph (g) of this clause.
(c) Copyright—(1) Data first produced in the performance of this contract. (i) Unless provided otherwise in paragraph (d) of this clause, the Contractor may, without prior approval of the Contracting Officer, assert copyright in scientific and technical articles based on data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings, or similar works. The prior, express written permission of the Contracting Officer is required to assert copyright in all other data first produced in the performance of this contract.

(ii) When authorized to assert copyright to the data, the Contractor shall affix the applicable copyright notices of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number).

(iii) For data other than computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government. For computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public) by or on behalf of the Government.

(2) Data not first produced in the performance of this contract. The Contractor shall not, without the prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract unless the Contractor—

(i) Identifies the data; and

(ii) Grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (g)(1)(ii) of this clause or, if such data are restricted computer software, the Government shall acquire a copyright license as set forth in paragraph (g)(1)(ii) of this clause (if included in this contract) or as otherwise provided in a collateral agreement incorporated in or made part of this contract.

(3) Removal of copyright notices. The Government will not remove any authorized copyright notices placed on data pursuant to this paragraph (c), and will include such notices on all reproductions of the data.

(d) Release, publication, and use of data. The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except—

(1) As prohibited by Federal law or regulation (including control or national security laws or regulations); (2) As expressly set forth in this contract; or

(3) If the Contractor receives or is given access to data necessary for the performance of this contract that contain restrictive markings, the Contractor shall treat the data in accordance with such markings unless specifically authorized otherwise in writing by the Contracting Officer or in the following paragraphs.

(4) In addition to any other provisions, set forth in this contract, the Contractor shall ensure that any resulting possible inventions made under this contract are 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 35 U.S.C. §§ 111, 115, 116, and 117, Patent Rights—Expedited Proceedings, and a patent application may be filed as a national application or as an international application under the Patent Cooperation Treaty. The Contractor shall submit to the Contracting Officer a statement that such data or publication is necessary to timely file a patent application in the absence of such time delay.

(2) As expressly set forth in this contract;

(e) Identification of data. (1) Unless specifically authorized otherwise in writing by the Contracting Officer, the data shall be identified as data first produced in the performance of this contract.

(ii) Grants to the Government, or acquires on its behalf, a license of the same scope as specified in paragraph (g)(3) or (4) of this clause or, if such data are restricted computer software, the Contractor授予 the Government a 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 to which the omitted markings apply.

(ii) If the Contractor fails to respond or fails to respond in a timely manner to a request made under this paragraph (e)(1)(ii), the Contractor is not precluded from using such data for the purpose for which they were provided, including screening, evaluation or optimization and for no other purpose.

(6) Confidentiality. (i) The Contractor shall take all reasonable precautions to maintain Confidential Information as confidential, but no less than the steps Contractor takes to secure its own confidential information.

(ii) Contractor shall maintain Confidential Information as confidential unless specifically authorized otherwise in writing by the Contracting Officer. Confidential Information includes, does not include, and is not necessarily protected by law including but not limited to any other provisions of this contract.

(7) Information Act. The Contractor may disclose the data to the extent the Government's interest in disclosure, use, or reproduction of such data is outweighed by the need of the Government to disclose, use, or reproduction of such data. The Contractor agrees that in accordance with paragraph (n) of this clause, the Contractor shall be used only for the purpose for which they were provided, including screening, evaluation or optimization and for no other purpose.

(e) 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.
Limited Rights Notice (SEPT 2014)

(a) These data are submitted with limited rights under Government Contract No. ____________ (and subcontract ____________, if appropriate). These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any, provided that the Government makes such disclosure subject to prohibition against further use and disclosure: Agencies may list additional purposes or if none, so state. (b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice)

Alternate III (Sept 2014). As prescribed in HHSAR 327.409, insert the following paragraph (g)(4) in the basic clause: (g)(4)(i) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of restricted computer software, or the Contracting Officer may require by written request the delivery of restricted computer software that has been withheld or would otherwise be entitled to be withheld. If delivery of that computer software is required, the Contractor shall affix the following “Restricted Rights Notice” to the computer software and the Government will treat the computer software, subject to paragraphs (e) and (f) of this clause, in accordance with the notice:

Restricted Rights Notice (SEPT 2014)

(a) This computer software is submitted with limited rights under Government Contract No. ____________ (and subcontract ____________, if appropriate). It may not be used, reproduced, or disclosed by any person except as provided in paragraph (b) of this notice or as otherwise expressly stated in the contract. (b) This computer software may be— (1) Used or copied for use with the computer(s) for which it was acquired, including use at any Government installation to which the computer(s) may be transferred; (2) Used or copied for use with a backup computer if any computer for which it was acquired is inoperative; (3) Reproduced for safekeeping (archives) or backup purposes; (4) Modified, adapted, or combined with other computer software, provided that the modified, adapted, or combined portions of the derivative software incorporating any of the delivered, restricted computer software shall be subject to the same restricted rights; (5) Disclosed to and reproduced for use by support service Contractors or their subcontractors in accordance with paragraphs (b)(1) through (4) of this notice; and (6) Used or copied for use with a replacement computer.

(c) Notwithstanding the foregoing, if this computer software is copyrighted computer software, it is licensed to the Government with the minimum rights set forth in paragraph (b) of this notice. (d) Any other rights or limitations regarding the use, duplication, or disclosure of this computer software are to be expressly stated in, or incorporated in, the contract. (e) This notice shall be marked on any reproduction of this computer software, in whole or in part.

(End of notice) (ii) Where it is impractical to include the Restricted Rights Notice on restricted computer software, the following short-form notice may be used instead:

Restricted Rights Notice Short Form (SEPT 2014)

Use, reproduction, or disclosure is subject to restrictions set forth in Contract No. ____________ (and subcontract, if appropriate) with (name of Contractor and subcontractor).
specific data deliverables listed as not subject to this paragraph, that the Contracting Officer may, up to 3 years after acceptance of all deliverables under this contract, inspect at the Contractor’s facility any data withheld pursuant to paragraph (g)(1) of this clause, for purposes of verifying the Contractor’s assertion of limited rights or restricted rights status of the data or for evaluating work performance. When the Contractor whose data are to be inspected demonstrates to the Contracting Officer that there would be a possible conflict of interest if a particular representative made the inspection, the Contracting Officer shall designate an alternate inspector.

(End of clause)

352.227–70 Publications and Publicity.

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

Publications and Publicity (DEC 2015)

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

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

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

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

(End of clause)

352.231–70 Salary Rate Limitation.

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

Salary Rate Limitation (DEC 2015)

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

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

(c) The salary rate limitation also applies to individuals in subcontract contracts.

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

(End of clause)

352.232–70 Incremental Funding.

As prescribed in HHSAR 332.706–2(b), the Contracting Officer shall insert the provision provided below in all solicitations when a cost-reimbursement contract for severable services using incremental funding is contemplated.

Incremental Funding (DEC 2015)

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

(End of provision)

352.233–71 Litigation and Claims.

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

Litigation and Claims (Dec 2015)

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

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

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

(End of clause)

352.236–70 Design-Build Contracts.

As prescribed in HHSAR 336.570(a), the Contracting Officer shall insert the following clause:
Design-Build Contracts (Dec 2015)

(a) General. (1) The contract constitutes and defines the entire agreement between the Contractor and the Government. This contract includes the standard or special contract clauses and schedules included at the time of award. This contract incorporates by reference:
   (i) The solicitation in its entirety (with the exception of instructions to offerors and evaluation criteria which do not become part of the award document);
   (ii) The specifications and statement of work;
   (iii) All drawings, cuts and illustrations, included in the solicitation and any amendments during all proposal phases leading up to award;
   (iv) Exhibits and other attachments; and
   (v) The successful Offeror’s accepted proposal.

(2) In the event of conflict or inconsistency between any of the requirements of the various contract clauses or schedules, precedence shall be given in the following order:
   (i) Betterments: Any portions of the Offeror’s proposal which exceed the requirements of the solicitation and which go beyond repair and improve the value of the property;
   (ii) The contract clauses and schedules included during the solicitation or at the time of award.

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

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

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

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

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

(3) The rights and remedies of the Government provided for under this contract are in addition to any other rights and remedies provided by law.

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

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

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

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

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

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

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

(i) Accident Prevention Plan;
(ii) Quality Control Plan;
(iii) Letter Appointing Superintendent;
(iv) Transmittal Register;
(v) Power of Attorney and Certified Copy of Resolution;
(vi) Network Analysis System, (when identified in the contract schedule as applicable);
(vii) List of Subcontractors;
(viii) SF 1413;
(ix) Performance and Payment Bonds; and
(x) Schedule of Values.

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

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

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

(g) Unscheduled jobsite shutdowns. Due to security reasons during the life of this contract the Government may on an unscheduled basis require the contractor to shut down its jobsite for 2 days per year at no additional cost. This shall not constitute a suspension of work under FAR 52.244–14. Suspension of Work (End of clause)

Alternate I (DEC 2015).

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

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

(i) Accident Prevention Plan;
(ii) Quality Control Plan;
(iii) Letter Appointing Superintendent;
(iv) Transmittal Register;
(v) Power of Attorney and Certified Copy of Resolution;
(vi) Network Analysis System, (when identified in the contract schedule as applicable);
(vii) List of Subcontractors;
(viii) SF 1413;
(ix) Performance and Payment Bonds; and
(x) Schedule of Values.

(3) A letter of record will be written documenting all items discussed at the conference, and a copy will be furnished by the Contracting Officer to all in attendance.
(3) No payment will be made for any in-place construction until all required submittals have been made, reviewed, and are satisfactory to the Government.

(End of clause)

352.237–70 Pro-Children Act.

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

Pro-Children Act (DEC 2015)

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

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

(End of clause)


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


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

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

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

(End of clause)


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

Indian Child Protection and Family Violence Act (DEC 2015)

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

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

(End of clause)

352.237–74 Non-Discrimination in Service Delivery.

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

Non-Discrimination In Service Delivery (DEC 2015)

It is the policy of the Department of Health and Human Services that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental). By acceptance of this contract, the contractor agrees to comply with this policy in supporting the program and in performing the services called for under this contract. The contractor shall include this clause in all sub-contracts awarded under this contract for supporting or performing the specified program and services. Accordingly, the contractor shall ensure that each of its employees, and any sub-contractor staff, is made aware of, understands, and complies with this policy.

(End of clause)
352.237-75 Key Personnel

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

**Key Personnel (DEC 2015)**

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

(End of clause)

352.239-73 Electronic Information and Technology Accessibility Notice.

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

**Electronic and Information Technology Accessibility Notice (Dec 2015)**

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 (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with the architectural and transportation barriers compliance board electronic and information technology (EIT) accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of provision)

352.239-74 Electronic Information Technology Accessibility.

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

**Electronic Information Technology Accessibility (DEC 2015)**


(b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must prepare any necessary updates to the HHS Section 508 Product Assessment Template(s) that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the individual. The request must identify the proposed replacement and provide an explanation of how the replacement’s skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of clause)
352.270–1 [Reserved]
352.270–2 [Reserved]
352.270–3 [Reserved]
352.270–4a Notice to Offerors, Protection of Human Subjects.

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

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


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

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

(c) Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.101(b)(1)–(6) are exempt from compliance with 45 CFR part 46. See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfjr46.html.

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

(e) In accordance with 45 CFR part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfjr46.html#46.111 for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at http://www.hhs.gov/ohrp/assurances/index.html).

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

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

(End of provision)

Alternate I (DEC 2015)

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

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

(End of provision)

352.270–4b Protection of Human Subjects.

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

Protection of Human Subjects (DEC 2015)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor’s current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.

(c) Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors’ FWA via designation as agents of the institution or via individual investigator agreements (see OHRP Web site at: http://www.hhs.gov/ohrp/policy/guidanceonaltfwafwa.pdf).

(d) If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer’s written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

(End of clause)

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

As prescribed in HHSAR 370.403(a), the Contracting Officer shall insert the following provision:
Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (DEC 2015)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1–4). In case of conflict between standards, the more stringent standard shall govern.

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United States Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1–2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1–4). In case of conflict between standards, the more stringent standard shall govern.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer’s written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor’s name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing with Animal Welfare Assurances.

Contracting Officer will request that OLAW provide assurance and verification of IACUC approval for the proposed animal activities prior to awarding a contract to an organization, including a faith-based organization, that the organization has a religious or moral objection, shall identify those work requirements it excluded to, become integrated with, or otherwise participate in a program or activity to which the organization has a religious or moral objection.

(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;

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

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

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

(c) The Government acknowledges that an offeror has specific rights, as cited in paragraph (b), to exclude certain work requirements in this solicitation from its proposal. However, the Government reserves the right not to make an award to an offeror whose proposal does not comply with the salient work requirements of the solicitation. Any exercise of that Government right will be made by the Head of the Contracting Activity.

(End of provision)

352.270–7 [Reserved]

352.270–8 [Reserved]

352.270–9 Non-Discrimination for Conscience.

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

Non-Discrimination for Conscience (DEC 2015)

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

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

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

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

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

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

(c) The Government acknowledges that an offeror has specific rights, as cited in paragraph (b), to exclude certain work requirements in this solicitation from its proposal. However, the Government reserves the right not to 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)
Notice to Offerors—Protection of Human Subjects. Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (DEC 2015)

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

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

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

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

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

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

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

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

(End of provision)


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

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

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

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

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

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

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

The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects under this contract, until RIHSC or its designee has reviewed and approved the proposed research protocol. The Contractor shall take the following actions:

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

(End of clause)

352.270–12 Needle Exchange.

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

Needle Exchange (DEC 2015)

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

(End of Clause)

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

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

Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research (DEC 2015)

(a) The Contractor shall not use any funds obligated under this contract for any abortion.

(b) The Contractor shall not use any funds obligated under this contract for the following:

(1) The creation of a human embryo or embryos for research purposes; or

(2) Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 209g(b)).
PART 353—FORMS

SUBCHAPTERS I—I [RESERVED]

SUBCHAPTER M—HHS SUPPLEMENTATIONS

PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

Subpart 370.1—[Reserved]

Subpart 370.2—[Reserved]

Subpart 370.3—Acquisitions Involving Human Subjects

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370.702 Solicitation provision.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2)

Subpart 370.3—Acquisitions Involving Human Subjects

370.300 Scope of subpart.

This subpart applies to all research activities conducted under contracts involving human subjects. See 45 CFR 46.102(d) and (f).

370.301 Policy.

It is the Department of Health and Human Services (HHS) policy that the contracting officer shall not award a contract involving human subjects until the prospective contractor provides assurance that the activity will undergo initial and continuing review by an appropriate Institutional Review Board (IRB) in accordance with HHS regulations at 45 CFR 46.103. The contracting officer shall require a Federal-wide assurance (FWA) approved by the HHS Office for Human Research Protections (OHRP), of each contractor, subcontractor, or institution engaged in human subjects research in performance of a contract. OHRP administers the assurance covering all HHS-supported or HHS-conducted activities involving human subjects.

370.302 Federal-wide Assurance (FWA).

(a) OHRP-Approved FWAs are found at the following Web site: http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc.

(b) Normally a contractor, subcontractor, or institution must provide approval of a FWA before a contract is awarded. If a contractor, subcontractor, or institution does not currently hold an approved FWA, it shall submit an explanation with its proposal and an FWA application prior to submitting a proposal. The contracting officer, on a case by case basis, may make award without an approved assurance in consultation with OHRP.

(c) A contractor, subcontractor, or institution must submit all FWAs, including new FWAs, using the electronic submission system available through the OHRP Web site at http://ohrp.cit.nih.gov/efile/, unless an institution lacks the ability to do so electronically. If an institution believes it lacks the ability to submit its FWA electronically, it must contact OHRP by telephone or email (see http://www.hhs.gov/ohrp/assurances/index.html) and explain why it is unable to submit its FWA electronically.

370.303 Notice to offerors.

(a) The contracting officer shall insert the provision at 352.270–4a, Notice to Offerors, Protection of Human Subjects, in solicitations, contracts, and orders involving human subjects.

(b) The contracting officer shall insert the provision at 352.270–10, Notice to Offerors—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, in solicitations that involve human subjects when the research is subject to RIHSC review and approval.

370.304 Contract clauses.

(a) The contracting officer shall insert the clause at 352.270–4b, Protection of Human Subjects, in solicitations, contracts, and orders involving human subjects.

(b) The contracting officer shall insert the clause at 352.270–6, Restriction on Use of Human Subjects, in contracts and orders if the contractor has an approved FWA of compliance in place, but cannot certify prior to award that an IRB registered with OHRP reviewed and approved the research, because definite plans for involvement of human subjects are not set forth in the proposal (e.g., projects in which human subjects’ involvement will depend upon completion of instruments, prior animal studies, or purification of compounds). Under these conditions, the contracting officer may make the award without the requisite certification, as long as the contracting officer includes appropriate conditions in the contract or order.

(c) For FDA, the contracting officer shall insert the clause at 352.270–11, Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, in contracts and orders that involve human subjects when the research is subject to RIHSC review and approval.

(d) The contracting officer shall insert the clause at 352.270–12, Needle Exchange, in solicitations, contracts, and orders involving human subjects.

(e) The contracting officer shall insert the clause at 352.270–13, Continued Ban on Funding Abortion and Continued Ban on Funding of Human
Embryo Research, in solicitations, contracts, and orders involving human subjects.

Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals

370.400 Scope of subpart.

This subpart applies to all research, research training, biological testing, housing and maintenance, and other activities involving live vertebrate animals conducted under contract. Additional information can be found in Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals http://grants.nih.gov/grants/olaw/references/phspolicy/animals.pdf.

370.401 Policy.

(a) It is HHS policy that contracting activities shall not award a contract involving live vertebrate animals until the Contractor provides acceptable assurance the contract work is subject to initial and continuing review by an appropriate Institutional Animal Care and Use Committee (IACUC) as described in the PHS Policy at IV.B.6 and 7. The contracting officer shall require an applicable Animal Welfare Assurance approved by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), of each contractor, subcontractor, or institution having responsibility for animal care and use involved in performance of the contract. Normally the assurance shall be approved before award. The contracting officer, on a case-by-case basis, may make award without an approved assurance in consultation with OLAW. For additional information see PHS Policy II., IV.A, and V.B.

(b) The OLAW, NIH, is responsible for negotiating assurances covering all HHS/PHS-supported or HHS/PHS-conducted activities involving the care and use of live vertebrate animals. OLAW shall provide guidance to contracting officers regarding adequate animal care and use, approval, disapproval, restriction, or withdrawal of approval of assurances. For additional information see PHS Policy V.A.


370.402 Assurances.

(a) Animal Welfare Assurances may be one of three types:

(1) Domestic Assurance (DA). A DA describes the institution’s animal care and use program, including but not limited to the lines of authority and responsibility, veterinary care, IACUC composition and procedures, occupational health and safety, training, facilities, and species housed. A DA listed in OLAW’s list of institutions with an approved DA is acceptable for purposes of this policy.

(2) Inter-institutional Assurance (IA). The offeror, its proposed subcontractor, or institution shall submit an IA when it does not have a proprietary animal care and use program, facilities to house animals or IACUC, and does not conduct animal research on-site. The offeror will perform the animal activity at an institution with an Animal Welfare Assurance named as a performance site. An IA approval extends to the full period of contract performance (up to 5 years) limited to the specific award or single project.

(3) Foreign Assurance (FA). The Foreign Assurance is required for institutions outside the U.S. that receive PHS funds directly through a contract award. The Foreign Assurance also applies to institutions outside the U.S. that receive PHS funds indirectly (named as a performance site). An FA listed in OLAW’s list of institutions with an approved FA is acceptable for purposes of this policy.

(b) The contracting officer shall forward copies of proposals selected for negotiation and requiring an assurance to OLAW at olawdoa@od.nih.gov, as early as possible to secure the necessary assurances.

(c) A contractor providing animal care services at an institution with an Animal Welfare Assurance, such as a Government-owned, Contractor-operated (GOCO) site, does not need a separate assurance. GOCO site assurances normally cover such contractor services.

370.403 Notice to offerors.

(a) The contracting officer shall insert the provision at 352.270–5a, Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, in solicitations involving live vertebrate animals.

(b) Offerors having a DA on file with OLAW shall submit IACUC approval of the use of animals in the manner required by the solicitation, but prior to award. The date of IACUC approval must not be more than 36 months prior to award.

(c) It is not necessary for offerors lacking an Animal Welfare Assurance to submit assurances or IACUC approval with proposals. OLAW shall contact contractors, subcontractors, and institutions to negotiate necessary assurances and verify IACUC approvals when requested by the contracting officer.

370.404 Contract clause.

The contracting officer shall insert the clause at 352.270–5b, Care of Live Vertebrate Animals, in solicitations, contracts, and orders that involve live vertebrate animals.

Subpart 370.5—[Reserved]

Subpart 370.6—[Reserved]

Subpart 370.7—Acquisitions Under the Leadership Act

370.700 Scope of subpart.


370.701 Solicitation provision.

The contracting officer shall insert the provision at 352.270–9, Non-Discrimination for Conscience, in solicitations valued at more than the micro-purchase threshold:

(a) In connection with the implementation of HIV/AIDS programs under the President’s Emergency Plan for AIDS Relief established by the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended; or
(b) Where the contractor will receive funding under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended. In resolving any issues or complaints that offerors may raise regarding meeting the requirements specified in the provision, the contracting officer shall consult with the Office of Global Health Affairs, Office of the General Counsel, the Program Manager, and other HHS officials, as appropriate.