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<AGENCY TYPE='S'>DEPARTMENT OF HEALTH AND HUMAN SERVICES

<CFR>48 CFR Chapter 3

<SUBJECT>Health and Human Services Acquisition Regulation

AGENCY: Department of Health and Human Services.

ACTION: Proposed rule.

SUMMARY: The Department of Health and Human Services (HHS) is proposing 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administrative and procedural in nature; to add or revise definitions; to correct certain terminology; and to delete outdated material or material duplicative of the FAR.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: Comments are due on or before May 1, 2015.

ADDRESSES: Submit comments in response to Health and Human Services Acquisition Regulation, parts 301 through 370 by any of the following methods:

Regulations.gov: http://www.regulations.gov. Submit comments via the Federal eRulemaking portal by entering "Health and Human Services Acquisition Regulation, parts 301 through 370" under the heading "Enter Keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds

with "Health and Human Services Acquisition Regulation, parts 301 through 370." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Health and Human Services Acquisition Regulation, parts 301 through 370" on your attached document.

Fax: 202-260-4823.

Mail: HHS/ASFR/OGAPA/Division of Acquisition, ATTN: Deborah Griffin, Room 537H, Hubert Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Instructions: Please submit comments only and cite Health and Human Services Acquisition Regulation, parts 301 through 370, in all correspondence related to this case. All comments received will be posted without change to http://www.regulations.gov.

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.

SUPPLEMENTARY INFORMATION:

<HD1>I. Background

The HHS made substantive changes in its Federal Acquisition Regulation (FAR) Supplement, the HHS Acquisition Regulation or HHSAR, in November 2009 (74 FR 62396 on November 27, 2009). On

April 26, 2010, HHS published in the Federal Register correcting amendments at 75 FR 2150. Since then numerous changes have been made to both statutory and regulatory (FAR) framework and requirements. Some of these new requirements were included in specific appropriations acts. This proposed rule changes the HHSAR to conform to these new requirements and to align the requirements with the current FAR. In addition, the procedural materials that were deemed internal or non-regulatory in nature are moved to internal procedures. Further changes are proposed to permit the various HHS operational divisions (OPDIVs) or staff divisions (STAFFDIVs) the necessary flexibility in meeting their respective missions. OPDIV provisions and clauses were collected and are tailored for department-wide application.

The updated HHSAR includes HHS initiatives designed to change the purpose and content of the HHSAR. The objective is to improve the efficiency and effectiveness of various phases of the acquisition lifecycle, creating the framework for innovation and maximum flexibility. The updated HHSAR will contain only requirements of law, HHS policies, delegations of FAR authorities, deviations from FAR requirements, and policies/procedures that have a significant effect beyond the internal procedures of HHS or a significant cost or administrative impact on entities pursuing business opportunities with HHS. The information removed from the HHSAR

consists of internal administrative and procedural information, referred to as internal procedures. In addition, the information removed does not have a significant effect beyond HHS internal operating procedures. The internal procedures will contain internal guidance, procedures, processes, and instructions but they will not be published in the Code of Federal Regulations. This framework which separates laws, policies, and other requirements impacting our industry partners from internal operating procedures will enable HHS to more rapidly convey internal administrative and procedural information to the acquisition workforce.

<HD1>II. Proposed Rule

The following summarizes changes to the HHSAR.

Part 301—HHS Acquisition Regulation System

Part 301 is revised as follows:

The nomenclature of the Contracting Officer's Technical Representative (COTR) was changed to Contracting Officer's Representative (COR) throughout the HHSAR. The training requirements for both Contracting Officers and CORs were deleted. The use of the term "project officer" has been removed throughout the HHSAR. The authority citations are corrected for all HHSAR parts.

The prescription at Section 301.106(c) (Office of Management and Budget approval under the Paperwork Reduction Act) regarding the Paperwork Reduction Act was moved to Part 311 and OMB clearance numbers were updated.

Section 301.270 (Executive Committee for Acquisition) is deleted as unnecessary for the regulation and reflecting only internal procedures.

Subpart 301.4 (Deviations from the FAR) is strengthened to enforce the appropriate use of deviations.

Subsection 301.602-3 (Ratification of unauthorized commitments), paragraph (b), is modified to strengthen the language.

Subpart 301.6 (Career Development, Contracting Authority, and Responsibilities) is extensively modified to make clear that all procurement authority stems from the SPE by delegation, ultimately, from the Head of the Agency, who can delegate authority to issue warrants to a level no lower than the HCA. The internal procedures were deleted.

Part 302—Definitions of Words and Terms

Part 302 is revised as follows:

Section 302.101 (Definitions) is revised to clarify roles and responsibilities with HHS organizational changes. Definitions that already appear in the FAR were removed as duplicative.

Subparts 302.70 (Common HHSAR Acronyms and Abbreviations) and 302.71 (HHS Standard Templates and Formats) are removed as unnecessary.

Part 303—Improper Business Practices and Personal Conflicts of Interest

Part 303 is revised as follows:

Subsection 303.104-7 (Violations or possible violations of the Procurement Integrity Act) is revised to remove internal procedures for processing a Procurement Integrity Act violation and to remove the requirement for a review by a Senior Executive Service employee.

Section 303.203 (Reporting suspected violations of the Gratuities clause) is revised to remove internal procedures for processing a report of a suspected violation.

Section 303.303 (Reporting suspected antitrust violations) is removed as internal procedures.

Subpart 303.4 (Contingent Fees) is deleted as unnecessary.

Subpart 303.10 (Contractor Code of Business Ethics and Conduct) is added to move Section 303.1003 (Requirements) to its proper subject placement and Section 303.1003 is revised to remove internal procedures for processing a report of a suspected violation of criminal law.

Part 304—Administrative Matters

Part 304 is revised as follows:

Section 304.602 (General) is modified to remove the internal procedures regarding contract reporting.

Section 304.604 (Responsibilities) is revised to remove the internal procedures and to note the importance of accuracy and timeliness in the Federal Procurement Data System reporting.

Subsection 304.803-70 (Contract/order file organization and use of checklists) is removed as unnecessary.

Subsection 304.804-70 (Contract closeout audits) is removed as unnecessary.

Subpart 304.13 (Personal Identity Verification) is removed as unnecessary and a policy statement is added for clarification.

Subpart 304.70 (Acquisition Instrument Identification Numbering System) is revised and renumbered as 304.16 (Unique Procurement Instrument Identifiers).

Subpart 304.71 (Review and Approval of Proposed Contract Actions) and Section 304.7100 (Policy) is revised to clarify contract reviews and to remove internal procedures.

Subpart 304.72 (Affordable Care Act Prevention and Public Health Fund—Reporting Requirements) is added to address information required by the Prevention and Public Health Fund (PPHF).

Part 305—Publicizing Contract Actions

Part 305 is revised as follows:

Subpart 305.2 (Synopsis of Proposed Contract Actions) is removed as unnecessary.

Section 305.303 (Announcement of contract awards), paragraph (a), is revised to remove a separate threshold for HHS and rely on the FAR. The internal procedures are removed.

Section 305.502 (Authority) is revised to remove language redundant to the FAR and to specify that published advertisements in print media require approval above the contracting officer.

Subpart 305.70 (Publicizing Requirements Funded from the Affordable Care Act Prevention and Public Health Fund) is added.

Part 306—Competition Requirements

Part 306 is revised as follows:

Section 306.202 (Establishing or maintaining alternative sources) is revised to include reference to the HHS Department Competition Advocate.

Subsection 306.302-1 (Only one responsible source and no other supplies or services will satisfy agency requirements), paragraph (a)(2)(iv), is deleted; the information is considered internal procedures. Also, information is added for the Bioshield Program.

Subsection 306.302-7 (Public interest) is revised to clarify the procedures for the signature of the Secretary for a determination and findings for public interest.

Section 306.303 (Justifications) is deleted; the information is considered internal procedures.

Section 306.304 (Approval of the justification) is deleted; the information is considered internal procedures.

Section 306.501 (Requirement) is revised to identify the HHS Department Competition Advocate.

Section 306.502 (Duties and responsibilities) is deleted; the information is considered internal procedures.

Part 307—Acquisition Planning

Part 307 is revised as follows:

Sections 307.104 (General procedures), 307.104-70 (Acquisition strategy), and 307.104-71 (Purpose and timing) are deleted.

Section 307.105 (Contents of written acquisition plans) is revised to clarify that HHS requires a written acquisition plan for all acquisitions above the simplified acquisition threshold.

Subsection 307.108-70 (Telecommuting of contractor employees) is deleted; this language is redundant; the FAR language is sufficient.

Subpart 307.70 (Considerations in Selecting an Award Instrument) is deleted; this information is considered internal procedures.

Subpart 307.71 (Acquisition Plan) is deleted; this information is considered internal procedures.

Part 308—Required Sources of Supplies and Services

Part 308 is revised as follows:

Section 308.404 (Use of Federal Supply Schedule) is deleted; the FAR language is sufficient.

Section 308.405-6 (Limited source justification and approval) is revised; information considered internal procedures is removed.

Subpart 308.8 (Acquisition of Printing and Related Supplies) is added to provide guidance on Government printing and electronic communications.

Part 309—Contractor Qualifications

Part 309 is revised as follows:

Section 309.402 (Policy) is deleted.

Section 309.403 (Definitions) is updated to provide current HHS definitions.

Section 309.404 (List of parties excluded from Federal procurement and non-procurement programs) is revised to change the title to System for Award Management (SAM) Exclusions. This revision reflects the current FAR language.

Section 309.405 (Effect of listing. Compelling Reason Determinations) is revised to change the title and updated to reflect current HHS terminology.

Sections 309.406 (Debarment) and 306.407 (Suspension) are revised.

Section 309.470 (Reporting of suspected causes for debarment or suspension or the taking of evasive actions) is revised to clarify and update the contracting officer's responsibilities to report and coordinate suspected causes for debarment or suspension or the taking of evasive actions.

Subsection 309.470-1 (Situations where reports are required) is revised and Subsection 309.470-2 (Contents of reports) is deleted; the information deleted is considered internal procedures.

Part 310—Market Research

Part 310 is revised as follows:

Section 310.001 (Policy) is revised to instruct contracting offices to follow the FAR.

Part 311—Describing Agency Needs

Part 311 is revised as follows:

Section 311.7000 (Defining electronic information technology (EIT) requirements) is revised to clarify the contracting officer's role in identifying the agency needs for EIT supplies and services; information considered internal procedures is deleted.

Section 311.7001 (Section 508 accessibility standards for HHS Web site content and communications materials) is moved to Part 339 and updated.

Subpart 311.71 (Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities) is relocated from Part 370.

Subpart 311.72 (Conference Funding and Sponsorship) is relocated from Part 370.

Subpart 311.73 (Contractor Collection of Information) is relocated from Part 301.

Part 312—Acquisition of Commercial Items

Part 312 is revised as follows:

Section 312.101 (Policy) is revised to emphasize that the HHS Strategic Sourcing Program shall be utilized when possible.

Section 312.202(d) (Market research and description of agency need) is revised to identify that the requiring activity specifies electronic and information technology (EIT) supplies and services subject to Section 508 and to move Section 508 requirements to Part 339.

Part 313—Simplified Acquisition Procedures

Part 313 is revised as follows:

Section 313.003 (Policy) is revised by moving language related to Section 508 to Part 339.

Subpart 313.1 (Procedures) is deleted; this language is duplicative of the FAR.

Section 313.301 (Government-wide commercial purchase card), paragraph (b), is revised to reference the HHS Purchase Card Program; the remaining procedural language is removed.

Section 313.303 (Blanket purchase agreements) and Subsection 313.305-5 (Purchases under blanket purchase agreements) are deleted; this information is not current.

Subpart 313.5 (Test Program for Certain Commercial Items) is deleted; this is considered procedural information.

Part 314—Sealed Bidding

Part 314 is revised as follows:

Section 314.103 (Policy) is revised by moving language related to Section 508 to Part 339.

Subpart 314.2 (Solicitation of Bids) is deleted; the FAR language is sufficient.

Subsection 314.404-1 (Cancellation of invitations after opening) in Section 314.404 (Rejection of bids) is revised to retain and clarify the HCA authority for rejection of bids and cancellations of invitations after opening.

Section 314.407 (Mistakes in bids) is revised to retain and clarify the head of the contracting activity authority for mistakes in bid both before award and afterward and information considered internal procedures is removed.

Part 315—Contracting By Negotiation

Part 315 is revised as follows:

The term "Technical Evaluation Panel" is removed and replaced with "Source Selection Evaluation Team" throughout this part and material that is deemed redundant to the FAR has been deleted.

Section 315.201 (Exchanges with industry before receipt of proposals) is determined to be internal procedures and is removed.

Subsection 315.204-5 (Part IV—Representations and instructions), paragraph (c)(2), is deleted and the internal procedures are removed.

Section 315.208 (Submission, modification, revision, and withdrawal of proposals) is revised to update how the Government will handle proposals after the exact time specified for receipt.

Section 315.209 (Solicitation Provisions and Contract Clauses) is deleted.

Section 315.304 (Evaluation factors and significant subfactors) is revised to move the text related to EIT acquisitions to Part 339, and the internal procedures are removed.

Section 315.305 (Proposal evaluation) is revised and the internal procedures are removed.

Sections 315.306 (Exchanges with offerors after receipt of proposals) and 315.307 (Proposal revisions) are removed.

Section 315.370 (Finalization of details with the selected source) is deleted as unnecessary; it is redundant to FAR 15.206.

Section 315.371 (Contract preparation and award) contains internal procedures which are removed.

Section 315.372 (Preparation of negotiation memorandum) contains internal procedures which are removed.

Subsection 315.404-2 (Information to support proposal analysis) is revised and internal procedures are removed.

Subsection 315.404-4 (Profit) is revised and the internal procedures related to developing weighted guidelines are removed.

Section 315.605 (Content of unsolicited proposals) is revised to clarify the requirements on the submitter of an unsolicited proposal. The requirement for a certification has been deleted and a warranty has been added to conform to current Federal law. This changes the government's remedy from a criminal sanction to a contract remedy.

Subsection 315.606-1 (Receipt and initial review) is revised for clarity.

Section 315.609 (Limited Use of Data) is deleted.

Subpart 315.70 (Acquisition of Electronic Information Technology) is moved to Part 339.

Part 316—Types of Contracts

Part 316 is revised as follows:

Section 316.603 (Letter contracts) is revised to limit letter contract modifications as prescribed in the FAR.

Section 316.307 (Contract clauses) is revised to clarify the application of the cost principle in accordance with the governing statute.

Section 316.505 (Ordering) is revised to clarify the role of the Competition Advocate as the task order ombudsman.

Subsection 316.603-70 (Procedure for requesting authority to issue a letter contract) is deleted as unnecessary.

Subsection 316.603-71 (Approval for modifications to letter contracts) is moved to 316.603-3 in part and is otherwise deleted as unnecessary.

Subpart 316.7 (Agreements) is deleted as unnecessary.

Part 317—Special Contracting Methods

Part 317 is revised as follows:

Section 317.104 (General) is revised to identify the Senior Procurement Executive as the designated agency approving official.

Subsection 317.105-1 (Uses), paragraph (a), is revised to update current thresholds for cancellation ceilings.

Section 317.107 (Options) is revised to update guidance on the use of options for multi-year contracts.

Section 317.204 (Contracts), paragraph (e), is revised to provide guidance on contract periods exceeding the 5-year limitation provided in FAR 17.204(e).

Section 317.207 (Exercise of Options) is deleted; the information for current Section 508 policy is provided in Part 339.

Subpart 317.5 (Interagency Acquisitions Under the Economy Act) is deleted; this information is considered internal procedures.

Subpart 317.70 (Multi-agency and Intra-agency Contracts) is deleted; this information is considered internal procedures.

Part 319—Small Business Programs

Part 319 is revised as follows:

Section 319.201 (General policy) language is revised to align with the FAR.

Subsection 319.202-2 (Locating small business sources) is removed as unnecessary.

Subsection 319.270-1 (Mentor Protégé Program) is revised to change the section heading to "Mentor Protégé Program Solicitation provision and contract clause."

Subpart 319.5 (Set-asides for Small Business) is deleted; the FAR coverage is sufficient.

Subpart 319.7 (Subcontracting with Small Business, Small Disadvantaged Business, and Women-Owned Small Business Concerns) is removed as unnecessary.

Part 322—Application of Labor Laws to Government Acquisitions

Part 322 is revised as follows:

Section 322.810 (Solicitation provisions and contract clauses) is revised to correct the clause prescriptions.

Part 323—Environment, Energy and Water Efficiency, Renewable Energy Technologies, Occupational Safety, and Drug-Free Workplace

Part 323 is revised as follows:

Section 323.7000 (Scope of subpart) is revised to clarify the applicable policy for safety and health situations.

Section 323.7001 (Policy) is revised to clarify guidance for safety and health situations.

Section 323.7002 (Actions required) is revised by removing information regarding roles other than the contracting officer.

Subpart 323.71 (Sustainable Acquisition Requirements) is revised by adding sustainable acquisition requirements. This additional information provides policy and a new provision prescription for offerors to describe their approaches for meeting the requirements of FAR 23.1 (Sustainable Acquisition Policy).

Part 324—Protection of Privacy and Freedom of Information

Part 324 is revised as follows:

Sections 324.000 (Scope of subpart) and 324.102 (General) are removed; this information is considered internal procedures.

Section 324.103 (Procedures) is revised to change the section heading to "Procedures for the Privacy Act" and to ensure that the statement of work/performance work schedule specifies the system of record and the disposition of the system of record.

Section 324.104 (Restrictions on Contractor Access to Government or Third Party Information) is added to provide information on restrictions on contractor access to Government or third party information.

Section 324.105 (Contract clauses) is added to prescribe the clause at 352.224-70 (Privacy Act) and 352.224-71 (Confidential Information).

Subpart 324.2 (Freedom of Information Act) is deleted; the FAR is sufficient.

Subpart 324.70 (Health Insurance Portability and Accountability Act of 1996 (HIPAA)) is added to provide coverage for the Health Insurance Portability and Accountability Act of 1996 and subtitle D of title IV of the Health Information Technology for Economic and Clinical Health Act (HITECH Act).

Pursuant to the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (August 21, 1996) and the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Investment Act, Public Law 111-5 (February 17, 2009), the Department issued regulations at 45 CFR parts 160 to 164 (HIPAA Rules).

The HIPAA Rules apply to "covered entities" and in part to "business associates," as defined at 160.103. Covered entities are health plans, health care clearinghouses, and any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under the HIPAA statute. In general, business associates are persons or organizations that perform certain functions or activities on behalf of, or provides certain services to, covered entities that involve the use or disclosure of protected health information. When covered entities use contractors to perform services or activities that involve protected health information, the HIPAA Privacy and Security Rules require that covered entities enter into an

agreement with business associates, commonly called business associate agreements, which must include specified terms set forth in these rules.

A covered entity that is a single legal entity and that conducts both covered and non-covered functions may elect to be a "hybrid entity," as defined at 164.103. A covered function is an activity that makes a person or organization a covered entity. To be a hybrid entity, a covered entity must designate in writing its operations that perform covered functions as one or more "health care components," as defined at 164.103. After making this designation, most of the requirements of the HIPAA rules will apply only to the health care components. A covered entity that is a hybrid entity must include a component that performs business associate-like activities within its health care component(s) so that such component is directly subject to the HIPAA Rules.

The Department is a covered entity. However, because the Department has elected to be a hybrid entity, most Department activities are not subject to the HIPAA Rules. At this time, the designated HHS' HCCs fall into the following categories: the CMS Medicare fee-for-service program, the Indian Health Service, the Commissioned Corps and the CDC World Trade Center Health Program. Even when a covered entity is a hybrid entity, the duty to enter into agreements or contracts that include certain terms remains with the covered entity rather than the health care component. For operational purposes it may be the covered entity's HCC(s) that perform the contract function on behalf of the covered entity.

This proposed rule references the terms that the HHS HCCs on behalf of the Department must include in their contracts with their business associates. In complying with the HIPAA Rules, the HCCs and their business associates shall interpret the HIPAA Rules consistent with the Department's interpretations as found on the HHS Office for Civil Rights website at http://www.hhs.gov/ocr/privacy. In particular, HCCs should reference the Sample Business Associate Agreement (BAA) Provisions at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html as they develop their business associate contracts.

The required business associate contract terms apply where the Department is required to enter into a business associate contract pursuant to the HIPAA Rules. We note that the

definition of business associate includes "subcontractors." However, under 45 CFR 164.502(e)(1)(i), a covered entity is not required to have a business associate contract with a subcontractor; this would be the responsibility of the business associate. Also, under 45 CFR 164.504(e)(3)(i)(A) and (B), the business associate contract terms are not required if the business associate is another government agency (e.g., a state agency) and certain conditions are met. Also, under 164.504(e)(3)(ii), the business associate contract terms are not required where the business associate is required by law to perform business associate functions or activities on behalf of the HCC or to provide certain services to a HCC, and certain other conditions are met. For example the Department of Justice is required by law to provide legal services to HHS.

Part 326—Other Socioeconomic Programs

Part 326 is added as follows:

Subpart 326.5 (Indian Preference in Employment, Training, and Subcontracting Opportunities) is added to provide information on the Indian preference in employment, training, and subcontracting opportunities. This information is moved from part 370.

Subpart 326.6 (Acquisitions Under the Buy Indian Act) is added to provide information on acquisitions under the Buy Indian Act. This information is moved from part 370.

Subpart 326.7 (Acquisitions Requiring the Native American Graves Protection and Repatriation Act) is added to provide information on acquisitions requiring the Native American Graves Protection and Repatriation Act. This information is moved from part 342.

Part 327—Rights, Data, and Copyrights

Part 327 is revised as follows:

Subsection 327.404-70 (Solicitation provision and contract clause), is revised to clarify that the contractor may publish results of its work.

Part 328—Bonds and Insurance

Part 328 is deleted; the FAR is deemed sufficient.

Part 330—Cost Accounting Standards

Part 330 is revised as follows:

Subsection 330.201-5 (Waiver) is revised and internal procedures are removed.

Part 331—Contract Cost Principles and Procedures

Part 331 is revised as follows:

Section 331.101-70 (Salary Rate Limitation) is revised to update how HHS appropriated funds are to be used, and direct users to Office of Personnel Management for the rate tables.

Section 331.102-70 (Pricing of adjustments) contains internal procedures and is removed.

Part 332—Contract Financing

Part 332 is revised as follows:

Section 332.402 (General) is revised to clarify the HCA responsibility for advance payments.

Section 332.403 (Applicability) is deleted as unnecessary.

Section 332.407 (Interest) is revised and internal procedures are removed.

Section 332.409 (Contracting Officer action) and Subsection 332.409-1 (Recommendation for approval) are deleted as unnecessary.

Section 332.702 (Policy), Section 332.703 (Contract funding requirements), and Subsection 332.703-71 (Incrementally funded cost-reimbursement contracts) are added to address contract funding issues.

Subsection 332.703-70 (Funding contracts during a continuing resolution) is removed since continuing resolution and their associated requirements change with each resolution.

Subsection 332.703-71 (Incrementally funded cost-reimbursement contracts) is added.

Subsection 332.703-72 (Incremental Funding Table) is added to provide a contract mechanism to track funding on an incrementally funded contract.

Section 332.704 (Limitation of cost or funds) is deleted as unnecessary.

Section 332.706 (Solicitation provision and contract clauses) is added to prescribe the clause at 352.232-70 (Incremental Funding).

Subsection 332.706-2 (Provision and clauses for limitation of cost or funds) is added to prescribe additional requirements for cost-reimbursement contract for severable services using incremental funding.

Part 333—Protests, Disputes, and Appeals

Part 333 is revised as follows:

Sections 333.102 (General) and 333.103 (Protests to the agency) are revised to remove internal procedures.

Sections 333.104 (Protests to GAO), 333.211 (Contracting Officer's decision), 333.212 (Contracting Officer's duties upon appeal), 333.212-70 (Formats), and 333.213 (Obligation to continue performance) are internal procedures and are deleted.

Subsection 333.215-70 (Contract clauses) is revised to reference the clause at 352.233-72 in all solicitations and contracts and to correct the clause prescriptions.

Part 334—Major System Acquisition

Part 334 is revised as follows:

Section 334.200 (Definitions) is deleted.

Section 334.201 (Policy) is revised to provide the HHS contract value thresholds for the requirement of EVMS.

Section 334.203 (Solicitation provisions and contract clauses) and Subsection 334.203-70 (HHS solicitation provisions and contract clauses) are deleted.

Part 335—Research and Development Contracting

Part 335 is revised as follows:

Subsection 335.070-1 (Policy) is revised to relax the prior mandates in order to provide the contracting officer more flexibility regarding cost-sharing contracts.

Subsection 335.070-2 (Amount of cost-sharing) is revised to provide the contracting officer more flexibility regarding fees or profits in cost-sharing contracts.

Subsection 335.070-4 (Contract award) is deleted as unnecessary.

Section 335.071 (Special determinations and findings affecting research and development contracting) is deleted as an unnecessary determinations and findings.

Section 335.072 (Key Personnel) is added to emphasize the importance of Key Personnel in research and development contracting.

Part 336—Construction and Architect-Engineer Contracts

Part 336 is added.

Part 337—Service Contracting - General

Part 337 is revised as follows:

Section 337.103 (Contracting Officer Responsibility) is revised as follows:

- Paragraphs (d)(1), (2), and (3), are revised to prescribe clauses to comply with Federal law.

- Paragraph (d)(4) is added to provide direction to the Indian Health Service contracting officers in complying with the Indian Child Protection And Family Violence Act (25 U.S.C. 3201 et seq.).

- **P**aragraph (e) is added to prescribe a clause that requires contractors who deliver services to beneficiaries of HHS programs to do so in a non-discriminatory fashion.

- Paragraph (f) is added to prescribe the use of the new key personnel clause at 352.237-75.

Section 337.103-70 (Solicitation provision and contract clause) is moved to Section 337.103 (Contracting Officer Responsibility) to align with FAR numbering.

Part 339—Acquisition of Information Technology

Revised Part 339 as follows:

Section 339.101 (Policy) is revised to clarify that contracting officers shall collaborate with the requiring activity for the acquisition of information technology supplies, services, and systems.

Section 339.201 (Clarification) and Subsection 339.201-70 (Required provision and contract clause) are deleted; the information is obsolete.

Section 339.203 (Approval of exceptions) is revised and the title is changed to (Applicability) to align with the FAR.

Sections 339.203-70 (Contract clauses), 339.204 (Exceptions), 339.204-1 (Approval of exceptions), and 339.205 (Section 508 accessibility standards for contracts) are added to provide updated information for electronic and information technology supplies and services and the requirements for compliance with Section 508 of the Rehabilitation Act.

Subparts 339.70 (Use of General Services Administration Blanket Purchase Agreements for Independent Risk Analysis Services) and 339.71 (Information Security Management) are internal procedures and are deleted.

Part 342—Contract Administration

Part 342 is revised as follows:

Section 342.302 (Contract administration functions) is revised as follows:

- Paragraph (c)(1) is deleted;

- Paragraph (c)(2) is deleted and the clause prescription is moved to Part 337 and renumbered;

- Paragraph (c)(3) is deleted because it prescribes the use of clause 352.242-71 (Tobacco-Free Facilities) which is also deleted; and

- Paragraph (c)(4) is deleted and the clause prescription is moved to Part 326 and renumbered.

Section 342.705 (Final indirect cost rates) is revised to clarify the HHS component named as the cognizant Federal agency within HHS.

Subpart 342.70 (Contract Monitoring) is revised by removing information from Sections 342.7000 (Purpose), 342.7001 (Contract monitoring responsibilities), and 342.7002 (Procedures to be followed when a contractor fails to perform); this information is considered internal procedures.

Section 342.7003 (Withholding of contract payments) is deleted; the FAR is sufficient.

Subpart 342.71 (Administrative Actions for Cost Overruns) is removed.

Part 352—Solicitation Provisions and Contract Clauses

Part 352 is revised as follows:

Clause 352.201-70 (Paperwork Reduction Act) is re-numbered 352.211-3 and relocated to Part 311.

Clause 352.202-1 (Definitions) is deleted.

Clause 352.203-70 (Anti-Lobbying) related to Subpart 303.8 (Limitation on the Payment of Funds to Influence Federal Transactions) is updated.

Clause 352.204-70 (Prevention and Public Health Fund – Reporting Requirements) is added.

Clause 352.208-70 (Printing and Duplication) is added.

Clause 352.211-1 (Accessibility of meetings, conferences, and seminars to persons with disabilities) formerly 352.270-7 is relocated from part 370.

Clause 352.211-2 (Conference sponsorship request and conference materials disclaimer) formerly 352.270-1 is relocated from Part 370.

Clause 352.211-3 (Paperwork Reduction Act) formerly 352.201-70 is relocated from part 301.

Clause 352.215-1 (Instructions to offerors – competitive acquisition) is deleted.

Clause 352.215-70 (Late Proposals and Revisions) is revised.

Clause 352.216-70 (Additional Cost Principles) is revised to correct the prescription citation.

Clause 352.219-70 (Mentor-protégé program) is revised.

Clause 352.222-70 (Contractor cooperation in equal employment opportunity investigations) is corrected.

Clause 352.223-70 (Safety and health) is updated.

Provision 352.223-71 (Instructions to Offerors—Sustainable Acquisition) is added.

Clause 352.224-70 (Privacy Act) is updated.

Clause 352.224-71 (Confidential Information) is added.

Clauses 352.226-1 (Indian Preference), 352.226-2 (Indian Preference Program), and 352.226-3 (Native American Graves Protection and Repatriation Act) are added. These clauses are moved from Parts 370 and 342 and renumbered.

Clause 352.227-70 (Publications and Publicity) is revised to clarify that the contractor may publish results of its work. In addition, paragraph (b) of the clause is revised. Paragraph "c" is added to clarify the advertising of products or services provided under the contract.

Clause at 352.231-70 (Salary Rate Limitation) is revised.

Clause 352.231-71 (Pricing of adjustments) is deleted as unnecessary.

Clause 352.232-70 (Incremental funding) is revised.

Clauses 352.233-70 (Choice of Law (overseas)) and 352.233-71 (Litigation and claims) are revised.

Provisions 352.234-1 (Notice of Earned Value Management System—Pre-Award Integrated Baseline Review) and 352.234-2 (Notice of Earned Value Management System—Post-Award Integrated Baseline Review) are deleted; the FAR provisions are sufficient.

Clauses 352.234-3 (Full Earned Value Management System) and 352.234-4 (Partial Earned Value Management System) are deleted; the FAR clauses are sufficient.

Clause 352.236-70 (Design-Build Contracts) is added with an Alternate I to be used for Fast Track procedures.

Clauses 352.237-70 (Pro-Children Act), 352.237-71 (Crime Control Act—reporting of child abuse), and 352.237-72 (Crime Control Act—requirement for background checks) are updated. Clauses 352.237-73 (Indian Child Protection and Family Violence Act), 352.237-74 (Non-discrimination in Service Delivery), and 352.237-75 (Key Personnel) are added.

Clause 352.239-70 (Standard for Security Configurations) is deleted; the clause is obsolete.

Clause 352.239-71 (Standard for Encryption Language) is deleted; the clause is obsolete.

Clause 352.239-72 (Security Requirements for Federal Information Technology Resources) is deleted; the clause is obsolete.

Provision 352.239-73 (Electronic and Information Technology and Accessibility Notice) is revised to provide updated information for electronic and information technology supplies and services and the requirements for compliance with Section 508 of the Rehabilitation Act.

Clause 352.239-74 (Electronic and Information Technology Accessibility) is added.

Clause 352.242-70 (Key Personnel) is renumbered as 352.237-75.

Clause 352.242-71 (Tobacco Free Facilities) is deleted. The clause is no longer necessary.

Clause at 352.242-72 (Native American Graves Protection and Repatriation Act) is renumbered as 352.236-3.

Clause 352.242-73 (Withholding of Contract Payments) is deleted; the FAR is sufficient.

Clause 352.242-74 (Final decisions on audit findings) is deleted; the FAR is sufficient.

Clause 352.270-1 (Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities) is moved to 352.211-1;

Clause 352.270-2 (Indian preference) is moved to 352.226-1.

Clause 352.270-3 (Indian preference program) is moved to 352.226-2.

Provision 352.270-4a (Notice to Offerors, Protection of Human Subjects) is revised to update the Federal-wide assurance requirement and provide for the inclusion of an Alternate to this provision.

Clause at 352.270-4b (Protection of Human Subjects) is revised to update the Federal-wide assurance requirement.

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

Clause 352.270-5b (Care of Live Vertebrate Animals) is updated.

Clause 352.270-6 (Restrictions on Use of Human Subjects) is revised to update the reference to the Institutional Review Board.

Clause 352.270-7 (Conference Sponsorship Request and Conference Materials Disclaimer) is moved to 352.211-2.

Clause 352.270-8 (Prostitution and related activities) is deleted.

Clause 352.270-9 (Non-discrimination for conscience) is updated.

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

Clause 352.270-11 (Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required) is added.

Clause 352.270-12 (Needle Exchange) is added.

Clause 352.270-13 (Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research) is added.

Part 353—Forms

Form HHS 674, Structured Approach Profit/Fee Objective is deleted. There are no forms; therefore, the part is reserved.

Part 370—Special Programs Affecting Acquisition

Part 370 is revised as follows:

Subpart 370.1 (Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities) is moved to part 311.

Subpart 370.2 (Indian Preference in Employment, Training, and Subcontracting Opportunities) is moved to part 326.

Subpart 370.3 (Acquisitions Involving Human Subjects) is revised to update the policy in section 370.301 and the Federal-wide assurance in 370.302.

Section 370.303 (Notice to offerors) is revised as follows:

- Paragraph (a) is revised to provide for the inclusion of an Alternate to the provision at 352.270-4a (Notice to Offerors, Protection of Human Subjects).

- Paragraph (d) is added to provide a prescription for the provision added at 352.270-10 (Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required) in FDA solicitations that involve human subjects research such that the research will be reviewed and approved by the Research Involving Human Subjects Committee (RIHSC).

Section 370.304 (Contract clauses) is revised as follows:

- Paragraph (c) is added to provide a prescription for the clause added at 352.270-11 (Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required) in FDA solicitations that involve human subjects research such that the research will be reviewed and approved by the Research Involving Human Subjects Committee (RIHSC).

- Paragraph (d) is added to provide a prescription for the clause added at 352.270-12 (Needle Exchange).

- Paragraph (e) is added to provide a prescription for the clause added at 352.270-13 (Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research).

Subpart 370.4 (Acquisitions Involving the Use of Laboratory Animals) is revised to update the policy in Section 370.401 (Policy) and the assurances in Section 370.402 (Assurances).

Sections 370.403 (Notice to offerors) and 370.404 (Contract clause) are revised to correct the provision and clause prescriptions.

Subpart 370.5 (Acquisitions Under the Buy Indian Act) is moved to part 326.

Subpart 370.6 (Conference Funding and Sponsorship) is moved to part 311.

Subpart 370.7 (Acquisitions under the Leadership Act) is revised for editorial corrections.

<HD1>III. Executive Order 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.

<HD1>IV. Regulatory Flexibility Act

These changes to the HHSAR will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act 5 U.S.C. 601, et seq. The proposed rule improves HHS acquisition by removing duplicative regulatory language, provisions and clauses, and procedural information, and provides departmental level regulation and provisions and clauses. Businesses, both small and large, can respond to uniform acquisition regulation, reducing their costs. As a result of these changes, the proposed rule should have a positive effect on small businesses allowing them to more readily compete for HHS contracts.

The Initial Regulatory Flexibility Analysis (IRFA) is summarized as follows:

INITIAL REGULATORY FLEXIBILITY ANALYSIS

This initial regulatory flexibility analysis has been prepared consistent with 5 U.S.C. 603.

1. Description of the reasons why action is being taken.

The Department of Health and Human Services (HHS) is proposing to amend its Federal Acquisition Regulation (FAR) Supplement, the HHS Acquisition Regulation (HHSAR), to update its regulation to current FAR requirements; to move internal guidance which is procedural in nature to Procedures, Guidance and Instructions (PGI), to add or revise definitions; to correct certain terminology and to delete outdated material or material duplicative of the FAR.

2. Statement of the objectives of, and the legal basis for, the rule.

HHS made substantive changes in its Federal Acquisition Regulation (FAR) Supplement, the HHS Acquisition Regulation or HHSAR, in November, 2009, (74 FR 62396 on November 27, 2009). On April 26, 2010, HHS published in the Federal Register correcting amendments at 75 FR 2150. Since then numerous changes have been made to both statutory and regulatory (FAR) framework and requirements. Some of these new requirements were included in specific appropriations acts. This publication of the proposed rule changes the HHSAR to conform to these new requirements and to align the requirements with the current FAR. In addition, the procedural materials that were deemed internal or non-regulatory in nature are moved to procedures, guidance, and instructions documents. Further changes are proposed to permit the various HHS operational divisions (OPDIVS) or staff divisions (STAFFDIVS) the necessary flexibility in meeting their respective missions. OPDIV provisions and clauses were collected and are tailored for department-wide application.

3. Description of and, where feasible, an estimate of the number of small entities to which the rule will apply.

HHS awarded approximately 95 thousand contract actions in FY2014; over 44 percent (42,232) 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 entities. The primary industry sectors affected are as represented in the chart below:

HHS FY2014 3-Digit NAICS Total Small Business Dollars	
221 (UTILITIES)	$485,385.87
236 (CONSTRUCTION OF BUILDINGS)	$164,277,302.92
325 (CHEMICAL MANUFACTURING) Total	$262,207,229.87
334 (COMPUTER AND ELECTRONIC PRODUCT MANUFACTURING)	$313,625,169.91
336 (TRANSPORTATION EQUIPMENT MANUFACTURING)	$66,756,387.08
339 (MISCELLANEOUS MANUFACTURING)	$29,127,192.37
423 (MERCHANT WHOLESALERS, DURABLE GOODS)	$33,254,853.30
424 (MERCHANT WHOLESALERS, NONDURABLE GOODS)	$21,355,796.73
443 (ELECTRONICS AND APPLIANCE STORES)	$69,190,516.74
493 (WAREHOUSING AND STORAGE)	$16,489,155.73
511 (PUBLISHING INDUSTRIES (EXCEPT INTERNET))	$49,671,265.41
517 (TELECOMMUNICATIONS)	$9,648,511.61
518 (DATA PROCESSING, HOSTING AND RELATED SERVICES)	$104,142,979.21
519 (OTHER INFORMATION SERVICES)	$36,729,861.34
524 (INSURANCE CARRIERS AND RELATED ACTIVITIES)	$7,734,506.42
531 (REAL ESTATE)	$2,107,755.53
541 (PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES)	$2,812,475,258.21
561 (ADMINISTRATIVE AND SUPPORT SERVICES)	$221,619,313.74
611 (EDUCATIONAL SERVICES)	$19,831,346.95
621 (AMBULATORY HEALTH CARE SERVICES)	$86,140,044.62
Total	**$4,326,869,833.56**

4. Description and estimate of compliance requirements including differences in cost, if any, for different groups of small entities.

The proposed rule will improve HHS acquisition by removing duplicative regulatory language, provisions and clauses, and procedures, guidance, and information (PGI) from HHS OPDIVS, and provides departmental level regulation, provisions and clauses, and PGI. This will enable businesses, both small and large, to respond to a uniform acquisition regulation and PGI,

reducing their costs and decreasing their burden for compliance. After removing outdated reporting requirements, HHS found there were fewer data collections with less burden than the current HHSAR contains. The remaining compliance requirements do not require an update to computer software, nor does it impose additional recordkeeping or reporting responsibilities. As a result of these changes, the proposed rule should have a positive effect on small businesses allowing them to more readily compete for HHS contracts. There are no differences anticipated for the costs for compliance requirements for small businesses.

5. Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the rule.

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules. As detailed in #2 above, language has been updated to comply with current FAR requirements, added where appropriate and necessary to supplement FAR, and removed where duplicative of FAR.

6. Description of any significant alternatives to the rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the rule on small entities.

There are no viable alternatives. The rule is being amended to update the regulation to current FAR requirements and to delete outdated material so that the rule as a whole will be statutorily correct. As cited in paragraph 4 above, the economic burden on both large and small businesses will be decreased. Consideration was given to amending the HHSAR by prioritizing parts. It was determined that this would leave regulations in place that were outdated and inconsistent with FAR requirements governing one aspect of an acquisition, while another aspect would be done in accordance with updated regulation consistent with the FAR. The outdated and the updated regulation could be contradictory and certainly could result in acquisitions open to legal

controversy leading not only to delays in acquisitions, but also improper acquisitions. This would be beneficial to neither the Government nor industry, including small businesses. Therefore, it is believed that the approach taken of amending of the HHSAR in whole is the most practical and benefits both Government and industry.

The Department of HHS, Division of Acquisition (DA), will submit a copy of the Initial Regulatory Flexibility Analysis (IRFA) to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the DA. HHS invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

HHS will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 in correspondence.

<HD1>V. Paperwork Reduction Act

A. The Paperwork Reduction Act (44 U.S.C. chapter 35) applies. The proposed rule contains 6 information collection requirements. Accordingly, HHS has submitted requests for approval of the new information collection requirements concerning this rule to the Office of Management and Budget. The information collection requirements are discussed as follows:

1. HHSAR 311.7101(a) (Responsibilities) and the clause at 352.211-1 (Accessibility of meetings, conferences and seminars to persons with disabilities) require contractors to provide a plan describing the contractor's ability to meet the accessibility standards in 28 CFR part 36.

HHSAR 311.7202(b) (Responsibilities) and the clause at 352.211-2 (Conference sponsorship request and conference materials disclaimer) require contractors to provide funding disclosure and a content disclaimer statement on conference materials. As a result of these clauses, HHS contractors providing conference, meeting, or seminars services are required to provide specific information to HHS.

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows:

Respondents: 1157

Responses per respondent: 1

Total annual responses: 1157

Preparation hours per response: 1 hour

Total response burden hours: 1157 hours

Total annual cost of compliance: $47,668

2. HHSAR 311.7300 (Policy) and the clause at 352.211-3 (Paperwork Reduction Act) require contractors to not proceed with the collection of information on surveys, questionnaires, and other information requests until the contractor is provided an Office of Management and Budget (OMB) clearance from the contracting officer.

Public reporting burden for this collection of information is estimated to average 2.2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows:

Respondents: 20,088,262

Responses per respondent: 1

Total annual responses: 20,088,262

Preparation hours per response: 2.2

Total response burden hours: 9,021,953

Total annual cost of compliance: $371,704,464

3. HHSAR 337.103(d)(3) (Contracting Officer Responsibility) and the clause at 352.237-72 (Crime Control Act-Requirement for Background Checks) require persons engaged in a covered profession or activity under an HHS contract or subcontract to report any suspected child abuse incident. The report

requirement is provided by the Childhelp USA, National Child Abuse Hotline.

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows:

Respondents: 40

Responses per respondent: 4

Total annual responses: 160

Preparation hours per response: 1

Total response burden hours: 160

Total annual cost of compliance: $6,592

4. HHSAR 337.103(d)(4) (Contracting Officer Responsibility) and the clause at 352.237-73 (Indian Child Protection and Family Violence Act) require contractors to provide information for a background check.

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows:

Respondents: 40

Responses per respondent: 4

Total annual responses: 160

Preparation hours per response: 1

Total response burden hours: 160

Total annual cost of compliance: $6,592

5 HHSAR 370.301 (Policy), the provision at 352.270-4a (Protection of Human Subjects), the clause at 352.270-4b (Protection of Human Subjects), the provision at 352.270-10 (Notice to Offerors – Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required), and the clause at 352.270-11 (Protection of Human Subjects – Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required), require contractors to provide an acceptable federal-wide assurance to HHS when engaging in human subject research in performance of a contract.

Public reporting burden for this collection of information is estimated to average .50 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows:

Respondents: 4,644

Responses per respondent: 1

Total annual responses: 4,644

Preparation hours per response: .50

Total response burden hours: 2,322

Total annual cost of compliance: $95,666

6. HHSAR 370.401 (Policy), 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), and the clause at 352.270-5b (Care of Live Vertebrate Animals) require contractors to provide an acceptable animal welfare assurance.

Public reporting burden for this collection of information is estimated to average 2.7 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows:

Respondents: 36

Responses per respondent: 4

Total annual responses: 41

Preparation hours per response: 2.7

Total response burden hours: 111

Total annual cost of compliance: $4,573

B. Public comment is sought regarding: Whether the proposed collections of information are necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, and document identifier, to Information.collectionclearance@hhs.gov. Written comments and recommendations for the proposed information collections must be directed to the Office of the Secretary, Paperwork Clearance Officer at the above email address within 60-days of this notice.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

<LSTSUB><HED>List of Subjects in 48 CFR Parts 301 through 370

Government procurement.</LSTSUB>

<SIG><DATED>Dated: February 10, 2015.

<NAME>Angela Billups,
<TITLE>Associate Deputy Assistant Secretary for Acquisition.</SIG>

BILLING CODE 4150-24

For the reasons stated in the preamble, HHS proposes revising 48 CFR chapter 3, parts 301 through 370, as set forth below.

<HD1>Title 48—Federal Acquisition Regulations System

<CHAPTER><HED>CHAPTER 3—HEALTH AND HUMAN SERVICES

<SUBCHAPTER><HED>SUBCHAPTER A—GENERAL
PART 301—HHS ACQUISITION REGULATION SYSTEM
PART 302—DEFINITIONS OF WORDS AND TERMS
PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST
PART 304—ADMINISTRATIVE MATTERS

SUBCHAPTER B—COMPETITION AND ACQUISITION PLANNING
PART 305—PUBLICIZING CONTRACT ACTIONS
PART 306—COMPETITION REQUIREMENTS
PART 307—ACQUISITION PLANNING
PART 308—REQUIRED SOURCES OF SUPPLIES AND SERVICES
PART 309—CONTRACTOR QUALIFICATIONS
PART 310—MARKET RESEARCH
PART 311—DESCRIBING AGENCY NEEDS
PART 312—ACQUISITION OF COMMERCIAL ITEMS

SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES
PART 313—SIMPLIFIED ACQUISITION PROCEDURES
PART 314—SEALED BIDDING
PART 315—CONTRACTING BY NEGOTIATION
PART 316—TYPES OF CONTRACTS
PART 317—SPECIAL CONTRACTING METHODS

SUBCHAPTER D—SOCIOECONOMIC PROGRAMS
PART 319—SMALL BUSINESS PROGRAMS
PART 322—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS
PART 323—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE
PART 324—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION
PART 326—OTHER SOCIOECONOMIC PROGRAMS

SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS
PART 327—PATENTS, DATA, AND COPYRIGHTS
PART 328—BONDS AND INSURANCE

PART 330—COST ACCOUNTING STANDARDS
PART 331—CONTRACT COST PRINCIPLES AND PROCEDURES
PART 332—CONTRACT FINANCING
PART 333—PROTESTS, DISPUTES, AND APPEALS

SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING
PART 334—MAJOR SYSTEM ACQUISITION
PART 335—RESEARCH AND DEVELOPMENT CONTRACTING
PART 336—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS
PART 337—SERVICE CONTRACTING—GENERAL
PART 339—ACQUISITION OF INFORMATION TECHNOLOGY

SUBCHAPTER G—CONTRACT MANAGEMENT
PART 342—CONTRACT ADMINISTRATION

SUBCHAPTER H—CLAUSES AND FORMS
PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES
PART 353—FORMS

SUBCHAPTERS I, J, K AND L [RESERVED]

SUBCHAPTER M—HHS SUPPLEMENTATIONS
PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

SUBCHAPTER A—GENERAL

PART 301—HHS ACQUISITION REGULATION SYSTEM

Subpart 301.1 Purpose, Authority, and Issuance

Sec.

301.101 Purpose.
301.103 Authority.
301.106 Office of Management and Budget approval under the Paperwork Reduction Act.

Subpart 301.2—[Reserved]

Subpart 301.4—Deviations from the FAR

301.401 Deviations.

Subpart 301.6—Career Development, Contracting Authority, and Responsibilities

301.602 Contracting Officers.

301.602-3 Ratification of unauthorized commitments.
301.603 Selection, appointment, and termination of appointment of contracting officers.
301.603-1 General.

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

Subpart 301.1—Purpose, Authority, and Issuance

301.101 Purpose.

(a) The Department of Health and Human Services (HHS) Acquisition Regulation (HHSAR) establishes uniform HHS acquisition policies and procedures that implement and supplement the Federal Acquisition Regulation (FAR).

(b)(1) The HHSAR contains HHS policies that govern the acquisition process or otherwise control acquisition relationships between HHS' contracting activities and contractors. The HHSAR contains—

(i) Requirements of law;

(ii) HHS-wide policies;

(iii) Deviations from FAR requirements; and

(iv) Policies that have a significant effect beyond the internal procedures of HHS or a significant cost or administrative impact on contractors or offerors.

(2) Relevant internal procedures, guidance, and information not meeting the criteria in paragraph (b)(1) of this section are issued by HHS in other announcements, internal procedures, guidance, or information.

301.103 Authority.

(b) The Assistant Secretary for Financial Resources (ASFR) prescribes the HHSAR under the authority of 5 U.S.C. 301 and section 205(c) of the Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. 121(c)(2)), as delegated by the Secretary).

(c) The HHSAR is issued in the Code of Federal Regulations (CFR) as chapter 3 of title 48, Department of Health and Human Services Acquisition Regulation. It may be referenced as "48 CFR chapter 3."

301.106 Office of Management and Budget approval under the Paperwork Reduction Act.

(a) The Paperwork Reduction Act of 1980 (44 U.S.C 3501 et seq.) imposes a requirement on Federal agencies to obtain approval from the Office of Management and Budget (OMB) before collecting the same information from 10 or more members of the public.

(b) The following OMB control numbers apply to the information collection and recordkeeping requirements contained in this chapter:

HHSAR Segment	OMB Control Number
311.7101(a)	TBD
311.7300	TBD
327.404-70(c)	TBD
337.103(d)(3)	TBD

HHSAR Segment	OMB Control Number
337.103(d)(4)	TBD
370.301	TBD
370.401	TBD
352.211-1	TBD
352.211-3	TBD
352.227-71	TBD
352.237-72	TBD
352.237-73	TBD
352.270-4a	TBD
352.270-4b	TBD
352.270-10	TBD
352.270-11	TBD
352.270-5a	TBD
352.270-5b	TBD

<SUBPART><HED>Subpart 301.2—[Reserved]

<SUBPART><HED>Subpart 301.4—Deviations from the FAR

301.401 Deviations.

Contracting officers are not permitted to deviate from the FAR or HHSAR without seeking proper approval. With full acknowledgement of FAR 1.102(d) regarding innovative approaches, any deviation to FAR or the HHSAR requires approval by the Senior Procurement Executive (SPE).

<SUBPART><HED>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 Department 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><HED>PART 302—DEFINITIONS OF WORDS AND TERMS

<SUBPART><HED>Subpart 302.1—Definitions

Sec.

302.101 Definitions.

<AUTH><HED>Authority:<P> 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

<SUBPART><HED>Subpart 302.1—Definitions

302.101 Definitions.

(a) Agency head or head of the agency, unless otherwise stated, means the head of the Staff Division (STAFFDIV) or Operating Division (OPDIV).

(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, STAFFDIV or OPDIVs may designate CORs for firm fixed-price contracts or orders. COR's 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 a STAFFDIV or OPDIV or other HHS organization which has been delegated broad authority regarding the conduct of acquisition functions.

<PART><HED>PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

<SUBPART><HED>Subpart 303.1—Safeguards

Sec.

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.</CONTENTS>

<AUTH><HED>Authority:<P> 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

<SUBPART><HED>Subpart 303.1—Safeguards

303.101 Standards of conduct.

303.101-3 Agency regulations.

(a)(3) The HHS Standards of Conduct are prescribed in 45 CFR part 73.

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

(a)(1) The contracting officer shall submit to the head of the contracting activity (HCA) for review and concurrence the

determination (along with supporting documentation) that a reported violation or possible violation of the statutory prohibitions has no impact on the pending award or selection of a contractor for award.

(2) The contracting officer shall refer the determination that a reported violation or possible violation of the statutory prohibitions has an impact on the pending award or selection of a contractor, along with all related information available, to the HCA. The HCA shall—

(i) Refer the matter immediately to the Associate Deputy Assistant Secretary (DAS) for Acquisition for review, who may consult with the appropriate legal office representative and the Office of Inspector General as appropriate; and

(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 Associate DAS for Acquisition 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><HED>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 OGC Ethics Division for disposition.

<SUBPART><HED>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><HED>Subpart 303.7—Voiding and Rescinding Contracts

303.704 Policy.

(a) For purposes of implementing FAR subpart 3.7, the HCA (non-delegable) shall exercise the authorities granted to the "agency head or designee."

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 Office of Inspector General and the HCA.

(c)(2) The contracting officer shall specify the title of HHS' OIG hotline poster and the website 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

Sec.

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.

Subpart 304.70—[Reserved]

Subpart 304.71—Review and Approval of Proposed Contract Actions

304.7100 Policy.

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

Sec.

304.7200 Scope of subpart.
304.7201 Procedures.
304.7202 Contract clause.

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

Subpart 304.6—Contract Reporting

304.602 General.

Follow internal department procedures for reporting information to the Federal Procurement Data System (FPDS) and for resolving technical or policy issues relating to FPDS contract reporting.

304.604 Responsibilities.

The Department of Health and Human Services (HHS) acquisition officials and staff shall report their contract information in FPDS accurately and timely.

Subpart 304.13—Personal Identity Verification

304.1300 Policy.

To ensure compliance with Homeland Security Presidential Directive-12: Policy for a Common Identification Standard for Federal Employees and Contractors (HSPD-12) and the Presidential Cross Agency Priority for strong authentication, contracting officers shall provide in each acquisition those HSPD-12 requirements necessary for contract performance.

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 subpart 4.16.

Subpart 304.70—[Reserved]

Subpart 304.71—Review and Approval of Proposed Contract Actions

304.7100 Policy.

In accordance with internal Operating Division or Staff Division policy 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 Pub. L. 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), Pub. L. 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 Prevention and Public Health Fund, shall report information specified in the clause at 352.204-70, 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, Prevention and Public Health Fund—Reporting Requirements. 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 website at http://www.hhs.gov/open/recordsandreports/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 orders against

existing or new contracts issued under FAR subparts 8.4 and 16.5 that will be funded with PPHF funds. Contracting officers shall include this clause in any existing contract or order that will be funded with PPHF funds. This clause is not required for any contract or order which contains a prior version of the clause at 352.204-70.

SUBCHAPTER B—COMPETITION AND ACQUISITION PLANNING

PART 305—PUBLICIZING CONTRACT ACTIONS

Subpart 305.3—Synopses of Contract Awards

Sec.

305.303 Announcement of contract awards.

Subpart 305.5—Paid Advertisements

305.502 Authority.

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

305.7001 Scope.
305.7002 Applicability.
305.7003 Publicizing preaward.
305.7004 Publicizing postaward.

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

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.)

Subpart 305.5—Paid Advertisements

305.502 Authority.

Written approval at least one level above the contracting officer shall be obtained prior to placing advertisements or notices in newspapers.

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 all 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 website at http://www.hhs.gov/open/recordsandreports/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.

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 website at http://www.hhs.gov/open/recordsandreports/prevention/index.html no later than 5 days after the contract action occurs.

PART 306—COMPETITION REQUIREMENTS

Subpart 306.2—Full and Open Competition after Exclusion of Sources

Sec.

306.202 Establishing or maintaining alternative sources.

Subpart 306.3—Other Than Full and Open Competition

306.302 Circumstances permitting other than full and open competition.
306.302-1 Only one responsible source and no other supplies or services will satisfy agency requirements.
306.302-7 Public interest.

Subpart 306.5—Competition Advocates

306.501 Requirement.

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

Subpart 306.2—Full and Open Competition after Exclusion of Sources

306.202 Establishing or maintaining alternative sources.

(a) The reference to the "agency head" in FAR 6.202(a) shall mean the Department Competition Advocate (CA).

(b)(1) 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 CA (non-delegable) shall sign the D&F.

Subpart 306.3—Other than Full and Open Competition

306.302 Circumstances permitting other than full and open competition.

306.302-1 Only one responsible source and no other supplies or services will satisfy agency requirements. See FAR 6.302-1.

For acquisitions covered by 42 U.S.C. 247d-6a(b)(2)(A), "available from only one responsible source" shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources".

306.302-7 Public interest.

(a) Authority. (2) Agency head, in this instance, means the Secretary.

(c) Limitations. The contracting officer shall prepare a written request for approval and provide it through appropriate acquisition channels, including the head of the contracting activity and Associate Deputy Assistant Secretary for Acquisition, to the Secretary. The request shall include a D&F for the Secretary's signature that contains all pertinent

information to support the justification for using the authority in 41 U.S.C. 3304(a)(7), and a letter for the Secretary's signature notifying Congress of the determination to award a contract under that authority.

Subpart 306.5—Competition Advocates

306.501 Requirement.

The Department Competition Advocate for Health and Human Services (HHS) is located in the Division of Acquisition.

PART 307—ACQUISITION PLANNING

Sec.

307.105 Contents of written acquisition plans.

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

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 308.4—Federal Supply Schedules

Sec.

308.405-6 Limited source justification and approval.

Subpart 308.8—Acquisition of Printing and Related Supplies

308.800 Scope of subpart.
308.801 Definitions.
308.802 Policy.

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

Subpart 308.4—Federal Supply Schedules

308.405-6 Limited source justification and approval.

(d)(1) As required by Federal Acquisition Regulation (FAR) 8.405-1 or 8.405-2, the responsible program office must provide a written justification whenever it requests an acquisition under the Federal Supply Service program that restricts consideration of the number of schedule contractors or to an item peculiar to one manufacturer.

Subpart 308.8—Acquisition of Printing and Related Supplies

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 definitions apply to this subpart:

Acquiring agency's head or designee, as used in this subpart is the head of the contracting activity (HCA). The HCA

may make the required justifications or determinations and take the necessary actions specified in FAR 9.405, 9.406, and 9.407, only after obtaining the written approval of the Suspension or Debarment Official, as appropriate.

Suspension and Debarment Official means the Deputy Assistant Secretary for Grants and Acquisition Policy and Accountability.

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 HCA (non-delegable) may, with the written concurrence of the Suspension and Debarment Official, make the determination~~s~~ 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 for 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.

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

310.001 Policy.

The HHS contracting offices shall conduct market research 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 **(see part 339)**.

Subpart 311.71—Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities

311.7100 Policy.
311.7101 Responsibilities.
311.7102 Contract clause.

Subpart 311.72—Conference Funding and Sponsorship

311.7200 Policy.
311.7201 Funding and sponsorship.
311.7202 Contract clause.

Subpart 311.73—Contractor Collection of Information

311.7300 Policy.
311.7301 Contract clause.

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

Subpart 311.70—Section 508 Accessibility Standards

311.7000 Defining electronic and information technology requirements (see part 339).

The contracting officer shall ensure that requiring activities specify agency needs for electronic and information technology (EIT) supplies and services, and document market research document EIT requirements, and identify the applicable Section 508 accessibility standards. See FAR 11.002(f) and subpart 39.2.

Subpart 311.71—Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities

311.7100 Policy.

(a) It is HHS policy that all meetings, conferences, and seminars be accessible to persons with disabilities. For the purpose of this policy, accessibility is defined as both physical access to meeting, conference, and seminar sites, and access to aids and services enabling individuals with sensory disabilities to fully participate in meetings, conferences, and seminars.

(b) This policy applies to all contracts requiring contractors to conduct meetings, conferences, or seminars open to the public or involving HHS personnel, but not ad hoc meetings necessary or incidental to contract performance.

311.7101 Responsibilities.

(a) The contractor shall submit a plan assuring that any meeting, conference, or seminar held will meet or exceed the minimum accessibility standards set forth in 28 CFR part 36.

(b) The contracting officer representative (COR) shall obtain, review, and approve the contractor's plan submitted in response to paragraph (a) of the contract clause at 352.211-1, Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities; a consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars is

acceptable. Prior to approving the plan, the COR shall consult with the operating division (OPDIV) or other designated organization responsible for monitoring compliance with the Architectural Barriers Act of 1968 and the Americans with Disabilities Act of 1990, to ensure that the contractor's plan meets the accessibility requirements of the contract clause. The COR shall request the responsible organization review and determine the adequacy of the contractor's plan, and respond to the COR, in writing, within 10 working days of receiving the request.

311.7102 Contract clause.

The contracting officer shall insert the clause at 352.211-1, Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities, in solicitations, contracts, and orders requiring the contractor to conduct meetings, conferences, or seminars in accordance with 311.7100(b).

Subpart 311.72—Conference Funding and Sponsorship

311.7200 Policy.

HHS policy requires that all conferences the agency funds or sponsors shall: be consistent with HHS missions, objectives, and policies; represent an efficient and effective use of taxpayer funds; and withstand public scrutiny.

311.7201 Funding and sponsorship.

Funding a conference through a HHS contract does not automatically imply HHS sponsorship, unless the conference is funded entirely by the agency. Also, HHS staff attendance or participation at a conference does not imply HHS conference sponsorship. Accordingly, for non-conference contracts funded entirely by HHS prior to a contractor claiming HHS sponsorship, the contractor must provide the contracting officer a written request for permission to designate HHS the conference sponsor. The OPDIV or STAFFDIV (operating division or staff division) head, or designee, shall approve such requests. The determination on what constitutes a "conference contract" or a "non-conference contract" shall be made by the contracting officer.

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.

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

Subpart 312.1—Acquisition of Commercial Items—General

312.101 Policy.

Contracting offices shall use the HHS Strategic Sourcing Program to the maximum extent possible. See HHSAR part 307 (Acquisition Planning).

Subpart 312.2—Special Requirements for the Acquisition of Commercial Items

312.202(d) Market research and description of agency need.

Whenever a requiring activity specifies electronic and information technology (EIT) supplies and services subject to Section 508 of the Rehabilitation Act of 1973, as amended, the requiring activity shall acquire commercially available supplies and services to the maximum extent possible while ensuring Section 508 compliance. See part 339.

SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES

PART 313—SIMPLIFIED ACQUISITION PROCEDURES

Sec.

313.003 Policy.

Subpart 313.3—Simplified Acquisition Methods

313.301 Government-wide commercial purchase card.

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

313.003 Policy.

Electronic and information technology (EIT) supplies and services acquired pursuant to Federal Acquisition Regulation part 13 shall comply with Section 508 of the Rehabilitation Act of 1973, as amended. See part 339.

Subpart 313.3—Simplified Acquisition Methods

313.301 Government-wide commercial purchase card.

(b) Make all HHS transactions utilizing the Government-wide commercial purchase card in accordance with the HHS Purchase Card Program.

PART 314—SEALED BIDDING

Subpart 314.1—Use of Sealed Bidding

Sec.

314.103 Policy.

Subpart 314.4—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.

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

Subpart 314.1—Use of Sealed Bidding

314.103 Policy.

Electronic and information technology (EIT) supplies and services acquired using sealed-bid procedures shall comply with

Section 508 of the Rehabilitation Act of 1973, as amended. See part 339.

Subpart 314.4—Opening of Bids and Award of Contract

314.404 Rejection of bids.

314.404-1 Cancellation of invitations after opening.

(c) The head of the contracting activity (HCA) shall make the agency head determinations specified in FAR 14.404-1.

314.407 Mistakes in bids.

314.407-3 Other mistakes disclosed before award.

(e) The HCA has the authority to make determinations under paragraphs (a), (b), (c), and (d) of FAR 14.407-3.

314.407-4 Mistakes after award.

(c) The HCA has the authority to make administrative determinations in connection with alleged post-award mistakes.

PART 315—CONTRACTING BY NEGOTIATION

Subpart 315.2—Solicitation and Receipt of Proposals and Information

Sec.

315.204-5 Part IV—Representations and instructions.
315.208 Submission, modification, revision, and withdrawal of proposals.

Subpart 315.3—Source Selection

315.303-70 Policy.
315.304 Evaluation factors and significant subfactors.
315.305 Proposal evaluation.

Subpart 315.4—Contract Pricing

315.404 Proposal analysis.
315.404-2 Information to support proposal analysis.

Subpart 315.6—Unsolicited Proposals

315.605 Content of unsolicited proposals.
315.606 Agency procedures.
315.606-1 Receipt and initial review.

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

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 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 (HHS) 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 and 42 CFR part 52h; Substance Abuse and Mental

Health Services Administration—42 U.S.C. 290aa-3, and Agency for Healthcare Research and Quality—42 U.S.C. 299c-1.

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

315.605 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 Department of Health and Human Services 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.)

315.606 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.

315.606-1 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.

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

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, 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.

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

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 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 is the agency head for the purposes of FAR 17.108(a). Upon SPE approval of the determination required by 317.105-1(b)(1), the SPE 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 provide all the following information:

(i) Clearly explain the contract(s) and organization(s) covered by the request.

(ii) Support the need for and reasonableness of the extension.

(3) *Approval authority*. Requests to exceed the 5-year limitations specified in FAR 17.204(e) must be 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.
319.270-1 Mentor Protégé Program Solicitation provision and contract clause.

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

Subpart 319.2—Policies

319.201 General policy.

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

(e)(1) The Department of Health and Human Services (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.

319.270-1 Mentor Protégé Program Solicitation provision and contract clause.

(a) The contacting 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 contacting 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.

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

Subpart 322.8—Equal Employment Opportunity

322.810 Solicitation provisions and contract clauses.

(h) 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.
323.7103 Solicitation Provision.

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

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.

Contracting 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' 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.

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

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 any 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 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 which 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, or the COR, after 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 but shall not award the contract 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 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 or "PHI", as defined in 45 CFR 160.103 shall be administered in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended, subtitle D of title IV of the Health Information Technology for Economic and Clinical Health Act (HITECH Act), and the corresponding implementing regulations at 45 CFR parts 160 and 164. The term "HIPAA" is used in this part to refer to

the HIPAA and HITECH statutes and the implementing regulations. HIPAA includes standards and implementation specifications for the security and privacy of certain individually identifiable health information known as Protected Health Information (PHI).

324.7001 Policy on Compliance with HIPAA business associate contract requirements.

"HIPAA" refers to the provisions of part C of title XI of the Social Security Act, 42 U.S.C. 1320d et seq., section 264 of the Health Insurance Portability and Accountability Act of 1996, as amended, and subtitle D of title IV of the Health Information Technology for Economic and Clinical Health Act (HITECH Act), as amended, and the HIPAA Rules at 45 CFR parts 160 through 164. HHS is a HIPAA "covered entity" that is a "hybrid entity" as these terms are defined at §§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 §164.103, are subject to HIPAA. HHS' HCCs may utilize persons or entities known as "business associates," as defined at §160.103. Generally, "business associate" means a "person" as defined by §160.103 (including contractors, and third-party vendors, etc.) if or when the person or entity:

(a) Creates, receives, maintains, or transmits "protected health information" (PHI), as the term is defined at 160.103, on

behalf of an HHS HCC to carry out HHS HIPAA-covered functions; or

(b) Provides certain services to an HHS HCC that involves PHI. Where the Department as a covered entity is required by 45 CFR 164.502(e)(1) and 164.504(e) and, if applicable, §§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 §164.504(e)(2) and, if applicable, §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.

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.

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

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 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, Pub. L. 93-638, 88 Stat. 2205, 25 U.S.C. 450e(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 Pub. L. 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 Pub. L. 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 Pub. L. 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 Pub. L. 94-437 and Pub. L. 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 Pub. L. 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.

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. A bid guarantee or bid bond is required only when a performance or payment bond is required.

(d) Indian preference in employment, training and subcontracting. Contracts awarded under the Buy Indian Act are subject to the requirements of section 7(b) of the Indian Self-Determination and Education Assistance Act 25 U.S.C. 450e, which requires giving preference to Indians in employment, training, and subcontracting. The contracting officer shall include the Indian Preference clause specified in 326.505(a) in all Buy Indian solicitations and resultant contracts. The contracting officer shall use the Indian Preference Program clause specified in 326.505(b). The contracting officer shall follow all requirements specified in subpart 326.2 which apply to a Buy Indian acquisition (e.g., 326.604 and 326.605).

(e) Subcontracting. A contractor shall not subcontract more than 50 percent of the work under a prime contract 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.

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. When 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: synopsize 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.

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—RIGHTS, 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

327.404-70 Solicitation provision and contract clause.
327.409 Solicitation provision and contract clause.

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

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 clause 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 FAR 52.227-14 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.

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

Subpart 330.2—CAS Program Requirements

330.201 Contract requirements.

330.201-5 Waiver.

The Associate Deputy Assistant Secretary for Acquisition 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 Senior Procurement Executive.

PART 331—CONTRACT COST PRINCIPLES AND PROCEDURES

Subpart 331.1—Applicability

Sec.

331.101-70 Salary rate limitation.

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

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.

Subpart 332.7—Contract Funding

332.702 Policy.
332.703 Contract funding requirements.
332.703-1 General.
332.703-71 Incrementally funded cost-reimbursement contracts.
332.703-72 Incremental Funding Table.
332.706 Solicitation provision and contract clauses.
332.706-2 Provision and clauses for limitation of cost or funds.

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

Subpart 332.4—Advance Payments for Non-Commercial Items

332.402 General.

(e) The head of the contracting activity (HCA) (non-delegable) is the person responsible for compliance with Federal Acquisition Regulation (FAR) 32.402(e) and shall determine whether advance payments are in accordance with FAR 32.402.

332.407 Interest.

(d) The HCA (non-delegable) shall make the determinations in FAR 32.407(d).

Subpart 332.5—Progress Payments Based on Cost

332.501 General.

332.501-2 Unusual progress payments.

(a)(3) 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 OPDIV 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.

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:

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

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

(c) Specify the start and end dates for each increment of performance, as required by the "Limitation of Funds" clause at FAR 52.232-22.

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:

CLIN, Task Number, or Description	Start Date of Increment of Performance	End Date of Increment of Performance	Estimated Cost ($)	Fee ($) (as appropriate)	Estimated Cost Plus Fee ($)(as appropriate)
			[Total]	[Total]	[Total]

* 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.

Subpart 333.2—Disputes and Appeals

333.203 Applicability.
333.209 Suspected fraudulent claims.
333.215-70 Contract clauses.

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

Subpart 333.1—Protests

333.102 General.

(g)(1) The Office of General Counsel - General Law Division serves as the liaison for protests lodged with the Government Accountability Office (GAO); is designated as the office

responsible for all protests within the Department of Health and Human Services (HHS); and serves as the notification point with GAO for all protests.

(2) The contracting officer will follow the direction of the Operating Division's (OPDIV) protest control officer for responding to protests whether they are filed with GAO or directly with the contracting officer.

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 FAR 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 (CBCA) 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).

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

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 that has been determined by the cognizant Federal agency to be in compliance with the guidelines in ANSI/EIA-748.

(c) For cost or incentive contracts and subcontracts valued at less than $20 million—

(1) The application of earned value management is optional at the discretion of the program/project manager and is a risk-based decision that must be supported by a cost/benefit analysis; and

(2) A decision to apply earned value management shall be documented in the contract file.

(d) For firm-fixed-price contracts and subcontracts of any dollar value the application of earned value management is discouraged.

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.
335.070-3 Method of cost-sharing.
335.071 [Reserved]
335.072 Key personnel.

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

335.070 Cost-sharing.

335.070-1 Policy.

(a) Contracting activities should encourage contractors to contribute to the cost of performing research and development (R&D), through the use of cost-sharing contracts, where there is a probability that the contractor will receive present or future benefits from participation as described in FAR 16.303. Examples include increased technical know-how, training for employees, acquisition of equipment, development of a commercially viable product that can be sold in the commercial market and use of background knowledge in future contracts. Cost-sharing is intended to serve the mutual interests of the Government and its contractors by helping to ensure efficient utilization of the resources available for the conduct of R&D projects and by promoting sound planning and prudent fiscal policies of the contractor. The Government's interest includes positive impact on the community at large.

(b) The contracting officer should use a cost-sharing contract for R&D contracts, unless the contracting officer determines that a request for cost-sharing would not be appropriate.

(c) Any determination made by a contracting officer as described in this section shall be evidenced by appropriate documentation in the contract file.

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. Therefore, contractor cost participation 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.

(b) 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.

(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.

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 a 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 secondary education or library services; 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 Control Act of 1990 (42 U.S.C. 13041).

(4) Contracting officers supporting IHS 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

339.203 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). Requiring activities 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 website content and communications material (in any format, such as reports, documents, charts, posters, presentations, or video material) that is specifically intended for publication on, or delivery via, an HHS-owned or –funded website, or whether these types of deliverables can be made compliant by the Government through other means. For deliverables made compliant by the Government through other means, the contract should not include accessibility standards.

(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://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/Staff Division (OPDIV/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/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 paragraph 4.3, Section 508 Compliance Exceptions, of the HHS Section 508 policy;

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

(3) 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://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 website 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.

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

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 (FMS), Division of Cost Allocation, Program Support Center (PSC)), 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 (NIH) Division of Financial Advisory Services, shall establish indirect cost rates and similar rates for use in contracts awarded to for profit organizations.

SUBCHAPTER H—CLAUSES AND FORMS

PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Subpart 352.1—Instructions for Using Provisions and Clauses

Sec.

352.100 Scope of subpart.
352.101-70 Application of provisions and clauses.

Subpart 352.2—Texts 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.
352.211-1 Accessibility of meetings, conferences, and seminars to persons with disabilities.
352.211-2 Conference sponsorship request and conference materials disclaimer.

352.211-3 Paperwork Reduction Act.
352.215-70 Late proposals and revisions.
352.216-70 Additional cost principles.
352.219-70 Mentor-protégé program.
352.219-71 Mentor-protégé program reporting requirements.
352.222-70 Contractor cooperation in equal employment opportunity investigations.
352.223-70 Safety and health.
352.223-71 Instructions to Offerors-Sustainable Acquisition.
352.224-70 Privacy Act.
352.224-71 Confidential Information.
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352.226-1 Indian preference.
352.226-2 Indian preference program.
352.226-3 Native American Graves Protection and Repatriation Act.
352.227-11 Patent Rights—Exceptional Circumstances.
352.227-14 Rights in Data—Exceptional Circumstances.
352.227-70 Publications and publicity.
352.231-70 Salary rate limitation.
352.232-70 Incremental Funding.
352.233-70 Choice of law (overseas).
352.233-71 Litigation and claims.
352.236-70 Design-Build Contracts.
352.237-70 Pro-Children Act.
352.237-71 Crime Control Act—reporting of child abuse.
352.237-72 Crime Control Act—requirement for background checks.
352.237-73 Indian Child Protection and Family Violence Act.
352.237-74 Non-Discrimination in Service Delivery.
352.237-75 Key personnel.
352.239-73 Electronic Information and Technology Accessibility Notice.
352.239-74 Electronic Information and Technology Accessibility.
352.270-1 [Reserved]
352.270-2 [Reserved]
352.270-3 [Reserved]
352.270-4a Notice to Offerors, Protection of Human Subjects.
352.270-4b Protection of Human Subjects.
352.270-5a Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.
352.270-5b Care of Live Vertebrate Animals.

352.270-6 Restriction on use of Human Subjects.
352.270-7 [Reserved]
352.270-8 [Reserved]
352.270-9 Non-discrimination for conscience.
352.270-10 Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.
352.270-11 Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.
352.270-12 Needle Exchange.
352.270-13 Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.

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

Subpart 352.1—Instructions for Using Provisions and Clauses

352.100 Scope of subpart.

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

352.101-70 Application of provisions and clauses.

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

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

Subpart 352.2—Texts of Provisions and Clauses

352.203-70 Anti-lobbying.

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

ANTI-LOBBYING (DATE)

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

(a) Publicity or propaganda purposes;

(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

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

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

(End of clause)

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

As prescribed in HHSAR 304.7201, insert the following clause:

PREVENTION AND PUBLIC HEALTH FUND — REPORTING REQUIREMENTS (DATE)

(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), Pub. L. 111-148, sec. 4002. Section 220(b)(5) requires each contractor to report on its use of these funds under this contract. These reports will be made available to the public.

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

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

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

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

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

(4) Program or project title, if any.

(5) The Contractor shall report any subcontract funded in whole or in part with PPHF funding, that is valued at $25,000 or more. The Contractor shall advise the

subcontractor that the information will be made available to the public. The Contractor shall report:

(i) Name and address of the subcontractor.

(ii) Amount of the subcontract award.

(iii) Date of the subcontract award.

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

(End of clause)

352.208-70 Printing and Duplication.

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

PRINTING AND DUPLICATION (DATE)

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

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

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

352.211-1 Accessibility of meetings, conferences, and seminars to persons with disabilities.

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

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

The Contractor agrees as follows:

(a) Except for ad hoc meetings necessary or incidental to contract performance, the Contractor shall develop a plan to assure that any meeting, conference, or seminar held pursuant to this contract will meet or exceed the minimum accessibility standards set forth in 28 CFR Part 36. The Contractor shall submit the plan to the Contracting Officer Representative for approval prior to initiating action. The Contractor may submit a consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars in lieu of separate plans.

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

(End of clause)

352.211-2 Conference sponsorship request and conference materials disclaimer.

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

CONFERENCE SPONSORSHIP REQUEST AND CONFERENCE MATERIALS DISCLAIMER (DATE)

(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 311.7301, the Contracting Officer shall insert the following clause:

PAPERWORK REDUCTION ACT (DATE)

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

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

(End of clause)

352.215-70 Late proposals and revisions.

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

LATE PROPOSALS AND REVISIONS (DATE) 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.

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

ADDITIONAL COST PRINCIPLES (DATE)

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

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

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

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

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

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

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

(End of clause)

352.219-70 Mentor-protégé program.

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

MENTOR-PROTÉGÉ PROGRAM (DATE)

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

(b) The program consists of—

(1) Mentor firms—large businesses that:

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

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

(2) Protégé firms—firms that:

(i) Seek developmental assistance;

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

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

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

(End of provision)

352.219-71 Mentor-protégé program reporting requirements.

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

MENTOR-PROTÉGÉ PROGRAM REPORTING REQUIREMENTS (JANUARY 2010)

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

(End of clause)

352.222-70 Contractor cooperation in equal employment opportunity investigations.

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

CONTRACTOR COOPERATION IN EQUAL EMPLOYMENT OPPORTUNITY INVESTIGATIONS (DATE)

(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, e-mail address, and telephone number, if that employee has been identified as a witness in an EEO complaint or investigation.

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

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

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

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

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

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

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

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

(End of clause)

352.223-70 Safety and health.

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

SAFETY AND HEALTH (DATE)

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

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

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

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

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

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

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

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

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

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

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

(End of clause)

352.223-71 Instructions to Offerors—Sustainable Acquisition.

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

INSTRUCTIONS TO OFFERORS—SUSTAINABLE ACQUISITION (DATE)

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

(End of provision)

352.224-70 Privacy Act.

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

PRIVACY ACT (DATE)

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

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

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

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

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

(End of clause)

352.224-71 Confidential Information.

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

CONFIDENTIAL INFORMATION (DATE)

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

(b) Specific information or categories of information that the Government will furnish to the contractor, or that the contractor is expected to generate, which are confidential may be identified elsewhere in this contract. The Contracting

Officer may modify this contract to identify Confidential Information from time to time during performance.

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

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

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

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

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

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

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

352.226-1 Indian Preference.

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

INDIAN PREFERENCE (DATE)

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

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

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

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

(e) As used in this clause,

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

evidence within 30 days from the tribe concerned that the person is a member of the tribe.

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

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

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

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

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

(End of clause)

352.226-2 Indian Preference Program.

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

INDIAN PREFERENCE PROGRAM (DATE)

(a) In addition to the requirements of the clause of this contract entitled "Indian Preference," the Contractor agrees to establish and conduct an Indian preference program which will expand opportunities for Indians to receive preference for employment and training in connection with the work performed under this contract, and which will expand the opportunities for

Indian organizations and Indian-owned economic enterprises to receive a preference in the awarding of subcontracts. In this connection, the Contractor shall perform the following:

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

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

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

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

subcontracting opportunities shall provide an equitable opportunity for Indian firms to submit bids or proposals by including—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Indian reservation includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of

the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601 et seq.)

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

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

(d) The Contractor agrees to include the provisions of this clause, including this paragraph (d), in each subcontract awarded at any tier under this contract and to notify the Contracting Officer of such subcontracts.

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

(End of clause)

352.226-3 Native American Graves Protection and Repatriation Act.

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

NATIVE AMERICAN GRAVES PROTECTION AND REPATRIATION ACT
(DATE)

(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—

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

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

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

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

352.227-11 Patent Rights—Exceptional Circumstances.

Patent Rights—Exceptional Circumstances (Sept 2014)

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

(a) Definitions. As used in this clause—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) [Reserved]

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

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

(3) Greater Rights Determinations. The Contractor, or an employee-inventor after consultation by the Agency with the Contractor, may request greater rights than are provided in paragraph (b)(1) of this clause in accordance with the procedures of FAR paragraph 27.304-1(c). In addition to the considerations set forth in paragraph 27.304-1(c), the Agency may consider whether granting the requested greater rights will interfere with rights of the Government or any Third party

assignee or otherwise impede the ability of the Government or the Third party assignee to, for example, develop and commercialize new compounds, dosage forms, therapies, preventative measures, technologies, or other approaches with potential for the diagnosis, prognosis, prevention, and treatment of human diseases.

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

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

(c) Invention disclosure by Contractor. The Contractor shall disclose in writing each Subject Invention to the Agency Contracting Officer and to the Director, Division of Extramural Inventions and Technology Resources (DEITR), if directed by the Contracting Officer, as provided in paragraph (j) of this clause within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure to the Agency Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was Made and all inventors. It shall be sufficiently complete in technical detail to convey a clear

understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication, and if so, whether it has been accepted for publication at the time of disclosure.

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

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

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

educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

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

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

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

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

(f) Reporting on utilization of Subject Inventions in the event greater rights are granted to the Contractor. The Contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request under subparagraph b.3. has been granted by the Agency. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and such other data

and information as the Agency may reasonably specify. The Contractor also agrees to provide additional reports as may be requested by the Agency in connection with any march-in proceeding undertaken by the Agency in accordance with paragraph (h) of this clause. As required by 35 U.S.C. 202(c)(5), the Agency agrees it will not disclose such information to persons outside the Government without permission of the Contractor.

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

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

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

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

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

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

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

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

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

[Insert Agency Address]

Agency Invention Reporting Web site: http://www.iEdison.gov.

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

[Insert description of license to Class 2 inventions]

(End of clause)

352.227-14 Rights in Data—Exceptional Circumstances.

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

RIGHTS IN DATA—EXCEPTIONAL CIRCUMSTANCES (SEPT 2014)

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

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

Computer software—(i) Means (A) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

(B) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

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

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

Data means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as

financial, administrative, cost or pricing, or management information.

Form, fit, and function data means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For computer software it means data identifying source, functional characteristics, and performance requirements but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

Limited rights means the rights of the Government in limited rights data as set forth in the Limited Rights Notice in Alternate II paragraph (g)(3) if included in this clause. "Limited rights data" means data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.

Restricted computer software means computer software developed at private expense and that is a trade secret, is commercial or financial and confidential or privileged, or is copyrighted computer software, including minor modifications of the computer software.

Restricted rights, as used in this clause, means the rights of the Government in restricted computer software, as set forth in a Restricted Rights Notice of Alternate III paragraph (g)(4) if included in this clause, or as otherwise may be provided in a collateral agreement incorporated in and made part of this contract, including minor modifications of such computer software.

Technical data means recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including computer databases and computer software documentation). This term does not include computer software or financial, administrative, cost or pricing, or management data or other information incidental to contract administration. The term includes recorded information of a scientific or technical nature that is included in computer databases (See 41 U.S.C. 403(8)).

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

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

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

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

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

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

(2) The Contractor shall have the right to—

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

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

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

(iv) Protect from unauthorized disclosure and use those data that are limited rights data or restricted computer software to the extent provided in paragraph (g) of this clause.

(c) Copyright. (1) Data first produced in the performance of this contract. (i) Unless provided otherwise in paragraph (d) of this clause, the Contractor may, without prior approval of the Contracting Officer, assert copyright in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings, or similar works. The prior, express written permission of the Contracting Officer is required to assert copyright in all other data first produced in the performance of this contract.

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

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

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

(i) Identifies the data; and

(ii) Grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause or, if such data are restricted computer software, the Government shall acquire a copyright license as set forth in paragraph (g)(4) of this clause (if included in this contract) or as otherwise provided in a collateral agreement incorporated in or made part of this contract.

(3) Removal of copyright notices. The Government will not remove any authorized copyright notices placed on data pursuant

to this paragraph (c), and will include such notices on all reproductions of the data.

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

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

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

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

(4) In addition to any other provisions, set forth in this contract, the Contractor shall ensure that information concerning possible inventions made under this contract is not prematurely published thereby adversely affecting the ability to obtain patent protection on such inventions. Accordingly, the Contractor will provide the Contracting Officer a copy of any publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure. Upon the Contracting Officer's request the Contractor agrees to delay the public disclosure of such data or publication of a specified paper for a reasonable time specified by the Contracting Officer, not to exceed 6 months, to allow for the filing of domestic and international patent applications in accordance with Clause 352.227-11, Patent Rights—Exceptional Circumstances (abbreviated month and year of Final Rule publication).

(5) Data on Material(s). The Contractor agrees that in accordance with paragraph (d)(2), proprietary data on Material(s) provided to the Contractor under or through this contract shall be used only for the purpose for which they were provided, including screening, evaluation or optimization and for no other purpose.

(6) Confidentiality. (i) The Contractor shall take all reasonable precautions to maintain Confidential Information as

confidential, but no less than the steps Contractor takes to secure its own confidential information.

(ii) Contractor shall maintain Confidential Information as confidential unless specifically authorized otherwise in writing by the Contracting Officer. Confidential Information includes/does not include [Government may define confidential information here.]

(e) Unauthorized marking of data. (1) Notwithstanding any other provisions of this contract concerning inspection or acceptance, if any data delivered under this contract are marked with the notices specified in paragraph (g)(3) or (4) of this clause (if those alternate paragraphs are included in this clause), and use of the notices is not authorized by this clause, or if the data bears any other restrictive or limiting markings not authorized by this contract, the Contracting Officer may cancel or ignore the markings. However, pursuant to 41 U.S.C. 253d, the following procedures shall apply prior to canceling or ignoring the markings.

(i) The Contracting Officer will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings;

(ii) If the Contractor fails to respond or fails to provide written justification to substantiate the propriety of the markings within the 60-day period (or a longer time approved in writing by the Contracting Officer for good cause shown), the Government shall have the right to cancel or ignore the markings at any time after said period and the data will no longer be made subject to any disclosure prohibitions.

(iii) If the Contractor provides written justification to substantiate the propriety of the markings within the period set in paragraph (e)(1)(i) of this clause, the Contracting Officer will consider such written justification and determine whether or not the markings are to be cancelled or ignored. If the Contracting Officer determines that the markings are authorized, the Contractor will be so notified in writing. If the Contracting Officer determines, with concurrence of the head of the contracting activity, that the markings are not authorized, the Contracting Officer will furnish the Contractor a written determination, which determination will become the final Agency decision regarding the appropriateness of the markings unless the Contractor files suit in a court of

competent jurisdiction within 90 days of receipt of the Contracting Officer's decision. The Government will continue to abide by the markings under this paragraph (e)(1)(iii) until final resolution of the matter either by the Contracting Officer's determination becoming final (in which instance the Government will thereafter have the right to cancel or ignore the markings at any time and the data will no longer be made subject to any disclosure prohibitions), or by final disposition of the matter by court decision if suit is filed.

(2) The time limits in the procedures set forth in paragraph (e)(1) of this clause may be modified in accordance with Agency regulations implementing the Freedom of Information Act (5 U.S.C. 552) if necessary to respond to a request there under.

(3) Except to the extent the Government's action occurs as the result of final disposition of the matter by a court of competent jurisdiction, the Contractor is not precluded by this paragraph (e) from bringing a claim, in accordance with the Disputes clause of this contract, that may arise as the result of the Government removing or ignoring authorized markings on data delivered under this contract.

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

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

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

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

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

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

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

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

(ii) Correct any incorrect notices.

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

(i) Identify the data being withheld; and

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

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

(3) [Reserved]

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

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

(End of clause)

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

Limited rights data means data, other than computer software, developed at private expense that embody trade secrets or are commercial or financial and confidential or privileged.

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

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

LIMITED RIGHTS NOTICE (SEPT 2014)

(a) These data are submitted with limited rights under Government Contract No. ____ (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 327.409, insert the following paragraph (g)(4) in the basic clause: (g)(4)(i) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of restricted computer software, or the Contracting Officer may require by written request the delivery of restricted computer software that has been withheld or would otherwise be entitled to be withheld. If

delivery of that computer software is required, the Contractor shall affix the following "Restricted Rights Notice" to the computer software and the Government will treat the computer software, subject to paragraphs (e) and (f) of this clause, in accordance with the notice:

RESTRICTED RIGHTS NOTICE (SEPT 2014)

(a) This computer software is submitted with restricted rights under Government Contract No. ____ (and subcontract ____, if appropriate). It may not be used, reproduced, or disclosed by the Government except as provided in paragraph (b) of this notice or as otherwise expressly stated in the contract.

(b) This computer software may be—

(1) Used or copied for use with the computer(s) for which it was acquired, including use at any Government installation to which the computer(s) may be transferred;

(2) Used or copied for use with a backup computer if any computer for which it was acquired is inoperative;

(3) Reproduced for safekeeping (archives) or backup purposes;

(4) Modified, adapted, or combined with other computer software, provided that the modified, adapted, or combined portions of the derivative software incorporating any of the delivered, restricted computer software shall be subject to the same restricted rights;

(5) Disclosed to and reproduced for use by support service Contractors or their subcontractors in accordance with paragraphs (b)(1) through (4) of this notice; and

(6) Used or copied for use with a replacement computer.

(c) Notwithstanding the foregoing, if this computer software is copyrighted computer software, it is licensed to the Government with the minimum rights set forth in paragraph (b) of this notice.

(d) Any other rights or limitations regarding the use, duplication, or disclosure of this computer software are to be expressly stated in, or incorporated in, the contract.

(e) This notice shall be marked on any reproduction of this computer software, in whole or in part.

(End of notice)

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

RESTRICTED RIGHTS NOTICE SHORT FORM (SEPT 2014)

Use, reproduction, or disclosure is subject to restrictions set forth in Contract No. ____ (and subcontract, if appropriate) with ____ (name of Contractor and subcontractor).

(End of notice)

(iii) If restricted computer software is delivered with the copyright notice of 17 U.S.C. 401, it will be presumed to be licensed to the Government without disclosure prohibitions, with the minimum rights set forth in paragraph (b) of this clause.

Alternate IV (SEPT 2014). As prescribed in 327.409, substitute the following paragraph (c)(1) for paragraph (c)(1) of the basic clause:

(c) Copyright—(1) Data first produced in the performance of the contract. Except as otherwise specifically provided in this contract, the Contractor may assert copyright in any data first produced in the performance of this contract. When asserting copyright, the Contractor shall affix the applicable copyright notice of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number), to the data when such data are delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. For data other than computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. For computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public), by or on behalf of the Government.

Alternate V (SEPT 2014). As prescribed in 327.409, add the following paragraph (j) to the basic clause:

(j) The Contractor agrees, except as may be otherwise specified in this contract for specific data deliverables listed as not subject to this paragraph, that the Contracting Officer may, up to 3 years after acceptance of all deliverables under this contract, inspect at the Contractor's facility any data withheld pursuant to paragraph (g)(1) of this clause, for purposes of verifying the Contractor's assertion of limited rights or restricted rights status of the data or for evaluating work performance. When the Contractor whose data are to be inspected demonstrates to the Contracting Officer that there would be a possible conflict of interest if a particular representative made the inspection, the Contracting Officer shall designate an alternate inspector.

(End of clause)

352.227-70 Publications and publicity.

As prescribed in 327.404-70(a), the Contracting Officer shall insert the following clause:

PUBLICATIONS AND PUBLICITY (DATE)

(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 331.101-70(b), the Contracting Officer shall insert the following clause:

SALARY RATE LIMITATION (DATE)

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

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary," have the same meaning and are collectively referred to as "direct salary," in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs).

The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

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

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

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

(End of clause)

352.232-70 Incremental Funding.

As prescribed in 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 (DATE)

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)

352.233-70 Choice of law (overseas).

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

CHOICE OF LAW (OVERSEAS) (DATE)

This contract shall be construed in accordance with the substantive laws of the United States of America. By the execution of this contract, the Contractor expressly agrees to waive any rights to invoke the jurisdiction of local national courts where this contract is performed and agrees to accept the exclusive jurisdiction of the United States Civilian Board of Contract Appeals or the United States Court of Federal Claims for hearing and determination of any and all disputes that may arise under the Disputes clause of this contract.

(End of clause)

352.233-71 Litigation and claims.

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

LITIGATION AND CLAIMS (DATE)

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

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

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

Contractor may incur or be subject to by reason of any loss, injury or damage, to the person or to real or personal property of any third parties as may accrue during, or arise from, the performance of this contract.

(End of clause)

352.236-70 Design-Build Contracts.

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

DESIGN-BUILD CONTRACTS (DATE)

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

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

(ii) The specifications and statement of work;

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

(iv) Exhibits and other attachments; and

(v) The successful Offeror's accepted proposal.

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

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

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

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

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

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

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

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

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

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

(c) Sequence of design—construction. (1) After receipt of the Contract Award, the Contractor shall initiate design, comply with all design submission requirements, and obtain Government review of each submission. No construction may be started until the Government reviews the Final Design submission and determines it satisfactory for purposes of beginning construction. The Contracting Officer will notify the Contractor when the design is cleared for construction. The Government will

not grant any time extension for any design resubmittal required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

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

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

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

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

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

(i) Accident Prevention Plan;

(ii) Quality Control Plan;

(iii) Letter Appointing Superintendent;

(iv) Transmittal Register;

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

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

(vii) List of Subcontractors;

(viii) SF 1413;

(ix) Performance and Payment Bonds; and

(x) Schedule of Values.

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

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

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

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

(End of clause)

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

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

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

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

(End of clause)

352.237-70 Pro-Children Act.

As prescribed in 337.103-70(d)(1), the Contracting Officer shall insert the following clause:

PRO-CHILDREN ACT (DATE)

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

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

352.237-71 Crime Control Act—reporting of child abuse.

As prescribed in 337.103-70(d)(2), the Contracting Officer shall insert the following clause:

CRIME CONTROL ACT OF 1990—REPORTING OF CHILD ABUSE (DATE)

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

(b) The Act designates "covered professionals" as those persons engaged in professions and activities in eight different categories including, but not limited to, teachers, social workers, physicians, dentists, medical residents or interns, hospital personnel and administrators, nurses, health care practitioners, chiropractors, osteopaths, pharmacists, optometrists, podiatrists, emergency medical technicians, ambulance drivers, alcohol or drug treatment personnel,

psychologists, psychiatrists, mental health professionals, child care workers and administrators, and commercial film and photo processors. The Act defines the term "child abuse" as the physical or mental injury, sexual abuse or exploitation, or negligent treatment of a child.

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

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

(End of clause)

352.237-72 Crime Control Act—requirement for background checks.

As prescribed in 337.103-70(d)(3), the Contracting Officer shall insert the following clause:

CRIME CONTROL ACT OF 1990—REQUIREMENT FOR BACKGROUND CHECKS (DATE)

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

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

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

(End of clause)

352.237-73 Indian Child Protection and Family Violence Act.

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

INDIAN CHILD PROTECTION AND FAMILY VIOLENCE ACT (DATE)

(a) This contract is subject to the Indian Child Protection and Family Violence Act, Pub. L. 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. Pub. L. 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 337.103-70(e), the Contracting Officer shall insert the following clause in solicitations and contracts:

NON-DISCRIMINATION IN SERVICE DELIVERY (DATE)

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 337.103(f), the Contracting Officer shall insert the following clause:

KEY PERSONNEL (DATE)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The

Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of clause)

352.239-73 Electronic Information and Technology Accessibility Notice.

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

ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY NOTICE (DATE)

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

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/sec508/standards.htm .

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

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508

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

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

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

(End of provision)

352.239-74 Electronic and Information Technology Accessibility.

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

ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (DATE)

(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance

Board (also referred to as the "Access Board") in 36 CFR Part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/sec508/standards.htm .

(b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) The Section 508 accessibility standards applicable to this contract are:

_____

(Contract staff must list applicable standards)

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

(e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility

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

(End of clause)

352.270-1 [Reserved]

352.270-2 [Reserved]

352.270-3 [Reserved]

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

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

NOTICE TO OFFERORS, PROTECTION OF HUMAN SUBJECTS (DATE)

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

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

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived

from individually identifiable human subjects. 45 CFR Part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.

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

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

(e) In accordance with 45 CFR Part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: the risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111 for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP website (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 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 (DATE). As prescribed in 370.303(a), the Contracting Officer shall substitute the following paragraph (g) for paragraph (g) of the basic clause.

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

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

352.270-4b Protection of Human Subjects.

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

PROTECTION OF HUMAN SUBJECTS (DATE)

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

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

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

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

(End of clause)

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 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 (DATE)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (E-mail: olaw@od.nih.gov; Phone: 301-496-7163).

(End of provision)

352.270-5b Care of Live Vertebrate Animals.

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

CARE OF LIVE VERTEBRATE ANIMALS (DATE)

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

of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 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 sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

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

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

NOTE: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: ace@aphis.usda.gov; website: (http://www.aphis.usda.gov/animal_welfare).

(End of clause)

352.270-6 Restriction on use of Human Subjects.

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

RESTRICTION ON USE OF HUMAN SUBJECTS (DATE)

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

(End of clause)

352.270-7 [Reserved]

352.270-8 [Reserved]

352.270-9 Non-discrimination for conscience.

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

NON-DISCRIMINATION FOR CONSCIENCE (DATE)

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

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

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

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

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

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

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

(End of provision)

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

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

NOTICE TO OFFERORS—PROTECTION OF HUMAN SUBJECTS, RESEARCH INVOLVING HUMAN SUBJECTS COMMITTEE (RIHSC) APPROVAL OF RESEARCH PROTOCOLS REQUIRED (DATE)

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

(b) The Offeror shall have an acceptable Assurance of Compliance on file with the Office for Human Research Protections (OHRP),

whenever it submits a proposal to the FDA for research expected to involve human subjects. Direct questions regarding Federal-wide Assurance to OHRP. The Offeror's proposal shall include a copy of the acceptable Assurance of Compliance.

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

(1) The Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance, hereafter referred to as "the local IRB," shall review the proposed research protocol. A letter from the local IRB stating that the proposed research protocol has been reviewed and approved, and thus adequately protects the rights and welfare of human subjects involved, or a letter stating that the proposed research is exempt under 45 CFR 46.101(b) shall be submitted to the Contracting Officer.
(2) Upon award, the successful Offeror, hereafter "the Contractor," shall submit its proposed research protocol to the FDA's Research Involving Human Subjects Committee (RIHSC). The RIHSC or its designee will review and approve the research protocol to assure it adequately protects the rights and welfare of human subjects involved. The RIHSC or designee will also determine whether the proposed research is exempt under 45 CFR 46.101(b). The Contractor shall submit, to the Contracting Officer of record, a copy of the RIHSC's or its designee's letter stating that it reviewed and approved the proposed research protocol.

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

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

to RIHSC or its designee for a second review. The Contractor is encouraged to solicit the RIHSC's or its designee's input during the resubmission process.

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

(End of Provision)

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

As prescribed in 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 (DATE)

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

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

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

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

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

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

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

(c) The Contractor further agrees that:

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

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

(End of Clause)

352.270-12 Needle Exchange.

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

NEEDLE EXCHANGE (DATE)

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 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 (DATE)

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

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

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

(2) Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR Part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.

(c) The Contractor shall not use any Federal funds for the cloning of human beings.

(End of Clause)

PART 353—FORMS

Subpart 353.3—[Reserved]

SUBCHAPTERS I, J, K AND L [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 website: 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 website 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 that involve human subjects. The contracting officer shall use the clause with its Alternate I when the agency is prescribing a date later than the proposal submission by which the offeror must have an approved FWA.

(b) Institutions having an OHRP-approved FWA shall certify IRB approval of submitted proposals in the manner required by instructions for completion of the contract proposal; by completion of an OMB Form No. 0990-0263, Protection of Human Subjects Assurance Identification/IRB Certification/Declaration

of Exemption (Common Rule); or by letter indicating the institution's OHRP-assigned FWA number, the date of IRB review and approval, and the type of review (convened or expedited). The date of IRB approval must not be more than 12 months prior to the deadline for proposal submission.

(c) The contracting officer generally will not request FWAs for contractors, subcontractors, or institutions prior to selecting a contract proposal for negotiation. When a contractor submits an FWA, it provides certification for the initial contract period; no additional documentation is required. If the contract provides for additional years to complete the project, the contractor shall certify annually in the manner described in 370.303(b).

(d) For the Food and Drug Administration (FDA), the contracting officer shall insert the provision at 352.270-10, Notice to Offerors—Protection of Human Subjects, 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><HED>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/phspolicylabanimals.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.

(c) If using live vertebrate animals, HHS policy requires that offerors address the points in the Vertebrate Animal Section (VAS) of the Technical Proposal. Each of the points must be addressed in the VAS portion of the Technical Proposal. For additional information see PHS Policy and use Contract Proposal VAS Worksheet.
http://grants.nih.gov/grants/olaw/references/phspol.htm#InformationRequiredinApplications-ProposalsforAwardsSubmittedtoPHS and http://grants.nih.gov/grants/olaw/VAScontracts.pdf.

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><HED>Subpart 370.5—[Reserved]

<SUBPART><HED>Subpart 370.6—[Reserved]

<SUBPART><HED>Subpart 370.7—Acquisitions under the Leadership Act

370.700 Scope of subpart.

This subpart sets forth the acquisition requirements regarding implementation of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) programs under the President's Emergency Plan for AIDS Relief as established by the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended (Pub. L. 108-25, Pub. L. 110-293, Pub. L. 113-56).

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.

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