DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

48 CFR Parts 301, 302, 303, 304, 305, 306, 307, 309, 311, 312, 314, 315, 316, 319, 323, 324, 325, 330, 332, 333, 334, 335, 339, 342, 352, and 370

Acquisition Regulations

AGENCY: Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services is amending its acquisition regulations (HHSAR) to make administrative and editorial changes to reflect organizational title changes resulting from Office of the Secretary (OS) and Operating Division (OPDIV) reorganizations and to update or remove outdated text and references. The intent of the final rule is to bring the HHSAR up to date and to make the HHSAR consistent with the latest amendments to the Federal Acquisition Regulations (FAR).

DATES: *Effective Date:* December 20, 2006.

FOR FURTHER INFORMATION CONTACT: Katherine Hughes, Office of Acquisition Management and Policy, telephone (202) 690–7079, e-mail: *Katherine.Hughes@hhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The Department is not making significant amendments to the existing HHSAR. The amendments to the HHSAR concern internal procedural matters which are administrative in nature, and will not have a major effect on the general public or on contractors or offerors supporting the Department. The majority of the amendments address the following:

- HHS organizational title changes resulting from agency reorganizations.
- Eliminating procedural guidance no longer deemed necessary.
- Changing contracting review and approval authorities to situate them at levels more appropriate to simplification, streamlining, and empowerment.
- Updating the HHSAR to bring it in line with the latest amendments made to the Federal Acquisition Regulation (FAR).
- Clarifying authorities for selecting and terminating Contracting Officers.
- Establishing minimum training requirements for certain positions.
- Specifically referencing regulations of other Federal agencies.
- Updating the text of clauses required to be inserted in solicitations and contracts.

B. Comments on the Notice of Proposed Rulemaking

The Department published a Notice of Proposed Rulemaking (NPRM) on May 26, 2006 (70 FR 30520). The comment period closed on July 25, 2006. The Department received one comment from the public regarding section 352.270–8. The commenter stated that the Office for Human Research Protections (OHRP), which was cited as an office within the National Institutes of Health (NIH), is now an office in the Office of Public Health and Science (OPHS). Section 352.270–8 has been corrected in this final rule to refer to the new office location.

In addition, the Department's internal review of the NPRM has resulted in a number of editorial changes and corrections, none of which are substantive.

C. Regulatory Flexibility Act

The Department of Health and Human Service certifies this rulemaking will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because it does not impose any new requirements. Therefore, no regulatory flexibility statement has been prepared. Since this rule conveys existing acquisition policies or procedures and does not promulgate any new policies or procedures that would impact the public, it has been determined that this rule will not have a significant economic effect on a substantial number of small entities, and, thus, a regulatory flexibility analysis was not performed.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the HHSAR do not impose any record keeping or information collection requirements that require approval by the Office of Management and Budget under 44 U.S.C. 3501, *et seq.* Existing approvals cited in 48 CFR 301.106 remain in effect. The provisions of this regulation are issued under 5 U.S.C. 301; 40 U.S.C. 486(c).

E. Administrative Procedure Act Exception

This final rule imposes no new burdens on the public and merely updates, corrects, or clarifies existing regulations. Therefore, good cause exists under 5 U.S.C. 553(d) to dispense with the 30-day delay in the effective date requirement, and the Department of Health and Human Services is making the rule effective upon publication in the **Federal Register**.

List of Subjects in 48 CFR Chapter 3

Government procurement.

Dated: September 21, 2006.

Joe W. Ellis,

Assistant Secretary for Administration and Management.

Editorial Note: This document was received in the Office of the Federal Register on December 13, 2006.

■ Under the authority of 5 U.S.C. 301; 40 U.S.C. 486(c), the Department of Health and Human Services amends 48 CFR Chapter 3 as set forth below.

CHAPTER 3—HEALTH AND HUMAN SERVICES

■ 1. The authority citation for 48 CFR chapter 3, parts 301 through 370 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

PART 301—HHS ACQUISITION REGULATION SYSTEM

■ 2. Revise paragraph (b) of section 301.101 to read as follows:

301.101 Purpose.

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(b) The HHSAR implements FAR policies and procedures and provides additional policies and procedures that supplement the FAR to satisfy the needs of HHS.

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■ 3. Revise section 301.270 to read as follows:

301.270 Executive Committee for Acquisition.

(a) The Deputy Assistant Secretary for Acquisition Management and Policy has established the Executive Committee for Acquisition (ECA) to assist and facilitate the planning and development of departmental acquisition policies and procedures and to assist in responding to other agencies and organizations concerning policies and procedures impacting the Federal acquisition process.

(b) The ECA consists of members and alternates from the Division of Acquisition Policy (DAP), Agency for Healthcare Research and Quality, Centers for Medicare & Medicaid Services, Program Support Center, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration. The ECA is

chaired by the Director, Division of Acquisition Policy (DAP). All meetings will be held at the call of the Chair, and all activities will be carried out under the direction of the Chair.

(c) The purposes of the ECA are to:

(1) Advise and assist the Chair on major acquisition policy matters;

(2) Review and evaluate the overall effectiveness of existing policies and procedures and the impact of new acquisition policies, procedures, and regulations on current acquisition policies and procedures.

(d) The Chair will periodically issue a list of current members and alternates, including each person's name, title, organization, address, telephone number, and e-mail address. ECA members are responsible for apprising the Chair of any changes to the list.

■ 4. Revise section 301.403 to read as follows:

301.403 Individual deviations.

Requests for individual deviations to either the FAR or HHSAR shall be prepared in accordance with 301.470 and forwarded to the Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP).

■ 5. Revise section 301.404 to read as follows:

301.404 Class deviations.

Requests for class deviations to either the FAR or HHSAR shall be prepared in accordance with 301.470 and forwarded to the Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP).

■ 6. Amend section 301.470 by revising paragraph (a) to read as follows:

301.470 Procedure.

(a) Deviation requests shall be prepared in memorandum form and forwarded through the Head of the Contracting Activity (HCA) to the Director, Division of Acquisition Policy. A deviation may be requested verbally in an exigency situation; however, the request must be confirmed in writing as soon as possible.

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■ 7. Amend section 301.602–3 by revising paragraphs (b)(3), (e)(1), and (e)(2) to read as follows:

301.602–3 Ratification of unauthorized commitments.

* * * * *

(b) * * *

(3) Ratification authority for actions up to $100,000 may be redelegated by the HCA to the chief of the contracting office (CCO). No other redelegations are authorized.

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(e) *Procedures.* (1) The individual who made the unauthorized contractual commitment shall furnish the reviewing Contracting Officer all records and documents concerning the commitment and a complete written statement of facts, including, a description of the requirement, the estimated or agreed upon price, the funds citation, an explanation of why the contracting office was not used and why the proposed contractor was selected, a list of other sources considered, and a statement as to whether the contractor has commenced work.

(2) The Contracting Officer will review the submitted material and prepare it for ratification if it is determined that the commitment is ratifiable. The Contracting Officer shall forward the ratification document and the submitted material to the HCA or CCO with any comments or information which should be considered in evaluation of the request for ratification. If legal review is desirable, the HCA or CCO will coordinate the request for ratification with the Office of General Counsel, Business and Administrative Law Division.

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■ 8. Revise section 301.603 and 301.603–1 to read as follows:

301.603 Selection, appointment, and termination of appointment of Contracting Officers/Contract Specialists.

301.603–1 General.

(a) The appointment, selection, and termination of appointment of Contracting Officers/Contract Specialists shall be made by the HCA. This authority is not delegable. The procedures for the selection and appointment of Contracting Officers/Contract Specialists shall apply to anyone seeking a Contracting Officer warrant. OPDIV procedures shall be followed in the appointment and termination of Contracting Officers/Contract Specialists in offices that have Contracting Officers/Contract Specialists with dual signature warrants.

(b) Standard Form (SF) 1402, ''Certificate of Appointment,'' shall be used to appoint personnel in the 1102 series as Contracting Officers. It shall also be used for personnel in any other series who will obligate the Government to the expenditure of funds in excess of the micro-purchase threshold. The SF 1402 shall indicate the Contracting Officer's warrant level and threshold and any other limitations. The HCA may determine an alternate appointment document for appointments at or below the micropurchase threshold level. Contracting Officer warrants will be issued to civil service personnel only. A delegation of procurement authority shall be set forth in a memorandum that describes the spending limits and authority. Changes to appointments shall be made by issuing a new appointment document. Each appointment document shall be prepared and maintained in accordance with FAR 1.603–1 and shall state the limits of the individual's authority.

(c) An individual must be certified at the appropriate level as a prerequisite to being appointed as a Contracting Officer with authority to obligate funds in excess of the micro-purchase threshold (see 301.603–72). The HCA will determine and require training for individuals appointed as Contracting Officers/Contract Specialists at dollar levels below the micropurchase threshold. Individuals selected for Contracting Officer warrant authority must meet the education, training, and experience requirements that are established for the warrant level. An individual shall be appointed as a Contracting Officer only in instances where a valid organizational need is demonstrated. Factors to be considered in assessing the need for an appointment of a Contracting Officer include volume of actions, complexity of work, and structure of the organization.

(d) Contracting Officers (GS–1102's) shall not sign contracts or modifications to contracts which will result in the total amount of the contract exceeding their delegated warrant authority (as specified on the SF–1402). This includes Indefinite Delivery Indefinite Quantity (IDIQ) contracts. However, orders placed against an IDIQ may be issued by Contracting Officers up to their delegated authority provided that each order is separate and distinct.

(e) Employees delegated warrant authority are the only individuals legally authorized to bind the Government by executing contracts or signing determinations and findings required by the FAR. The amount specified on the warrant shall cover the estimated maximum contract amount, including all option periods. For example, an employee with a $500,000 Contracting Officer Certificate of Appointment may not award a contract for a base year of $300,000 if the contract includes a one-year option for an additional $300,000. In this case, the total contract amount, including options, exceeds the amount stipulated in the warrant. If a warrant is limited to $500,000 (for example), the holder may not sign a contract for more than that amount, even if the additional amount

is subject to the availability of funds. Contracting Officers with higher warrant levels may sign the action when modifications to orders and contracts make the total amount of the contract exceed the Contracting Officer's warrant limitation.

■ 9. Revise section 301.603–2 to read as follows:

301.603–2 Selection of Contracting Officers.

When it has been determined that the appointment is in the best interest of the OPDIV and/or Department and there is a demonstrated need for the procurement authority requested, nominations for appointment of Contracting Officers shall be submitted to the HCA through appropriate organizational channels for review. The HCA is responsible for appointing Contracting Officers in accordance with FAR 1.603. This authority is not delegable. The HCA will determine the documentation required, consistent with FAR 1.603–2, when the resulting appointment and authority will not exceed the micropurchase threshold.

■ 10. Revise section 301.603–3 to read as follows:

301.603–3 Appointment of Contracting Officers.

(a) Appointing officials must ensure that a warrant candidate meets the experience and education/training requirements listed in 301.603–72.

(b) If it is essential to appoint an individual who does not fully meet the certification requirements for the Contracting Officer authority sought, an interim appointment may be granted by the HCA. HCAs are responsible for ensuring that training requirements are met within the specified time frame. Interim appointments may not exceed one year in total, and shall not be granted unless the individual can meet the certification requirements within one year from the date of appointment. The HCA may extend an interim appointment by granting additional time to complete the requirements of a permanent appointment. If the certification requirements are not completed by the extended date, the appointment will automatically terminate.

■ 11. Revise section 301.603–4 to read as follows:

301.603–4 Termination or revocation of a Contracting Officer's appointment.

Termination or revocation of Contracting Officer appointments shall be accomplished in accordance with FAR 1.603–4.

■ 12. Revise section 301.603–70 to read as follows:

301.603–70 Delegation of Contracting Officer responsibilities.

(a) Contracting Officer responsibilities which do not involve the obligation or deobligation of funds or result in establishing or modifying contractual provisions may be delegated by the Contracting Officer by means of a written memorandum that clearly delineates the delegation and its limits.

(b) Contracting Officers may designate individuals as ordering officials to make purchases or place orders under blanket purchase agreements, indefinite delivery contracts, or other preestablished mechanisms. Ordering officials, including those under the National Institutes of Health's (NIH) Delegated Acquisition Program (DELPRO), are not Contracting Officers.

■ 13. Add sections 301.603–71 through 301.603–76 to subpart 301.6 to read as follows:

Subpart 301.6—Career Development, Contracting Authority, and Responsibilities

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301.603–71 Waivers to warrant standards.
301.603–72 Training and certification requirements for Contracting Officers/Contract Specialists.
301.603–73 Earned value training requirement for Contracting Officers/Contract Specialists who administer an IT contract.
301.603–74 Training policy exception.
301.603–75 Training requirement for purchase cardholders, Approving Officials (AOs), and Agency/Organization Program Coordinators (A/OPCs).
301.603–76 Requirement for certification retention and maintaining currency of acquisition knowledge and skills for Contracting Officers/Contract Specialists and purchasing agents.

Subpart 301.6—Career Development, Contracting Authority, and Responsibilities

301.603–71 Waivers to warrant standards.

There may be an unusual circumstance that requires delegation of a warrant to an employee who does not meet the warrant standards in of the HHS Contracting Officer Warrant Program. Any requests for waivers requesting deviations from the requirements and policies of the HHS Contracting Officer Warrant Program shall be sent in writing to the SPE for approval. The SPE will either approve or disapprove in writing the request for a waiver to the warrant standards. The SPE may grant waivers on a case-by-case basis in unique situations only.

301.603–72 Training and certification requirements for Contracting Officers/Contract Specialists.

(a) Federal Acquisition Certification in Contracting (FAC–C) certification is *not mandatory* for all GS–1102s; however, members of the workforce issued new Contracting Officer (CO) warrants on or after January 1, 2007, regardless of GS series, *must* be certified at an appropriate level to support their warrant obligations, pursuant to agency policy. *New* CO warrants are defined in OFPP Policy Letter 05–01 as warrants issued to employees for the *first time* at a department or agency. FAC–C certification does not apply to:

(1) Senior level officials responsible for delegating procurement authority;

(2) Non-1102s whose warrants are generally used to procure emergency goods and services; or

(3) Non-1102s whose warrants are so limited as to be outside the scope of this program, as determined by the Chief Acquisition Officer (CAO).

(b) HHS requires a senior level FAC–C certification for any employee issued an unlimited Contracting Officer's warrant on or after January 1, 2007.

(c) Achievement of the FAC–C is based on three requirements: education, training, and experience, and the requirements are cumulative, (i.e., a person must meet the requirements of each previous certification level).

(d) FAC–C training requirements are as follows:

(1) FAC–C Level I:

(i) CON 100 Shaping Smart Business Arrangements.

(ii) CON 110 Mission Support Planning.

(iii) CON 111 Mission Strategy Execution.

(iv) CON 112 Mission Performance Assessment.

(v) CON 120 Mission Focused Contracting.

(vi) 1 Elective.

(2) FAC–C Level II:

(i) CON 202 Intermediate Contracting.

(ii) CON 204 Intermediate Contract Pricing.

(iii) CON 210 Government Contract Law.

(iv) 2 Electives.

(3) FAC–C Level III:

(i) CON 353 Advanced Business Solutions for Mission Support.

(ii) 2 Electives.

(e) Those conducting simplified acquisitions from $2,500 to $100,000 will need to be issued an HHS Simplified Acquisition Certificate. Required training is as follows:

(1) HHS Simplified Acquisition Certificate A:

(ii) Basic Simplified Acquisition Procedures/DAU's CON 237.

(iii) Advanced Simplified Acquisition Procedures or Appropriations Law.

(2) HHS Simplified Acquisition Certificate B:

(i) Basic Simplified Acquisition Procedures/DAU's CON 237.

(ii) Advanced Simplified Acquisition Procedures or Appropriations Law.

(iii) CON 100 (Shaping Smart Business Arrangements).

(iv) CON 110 (Mission Support Planning).

(f) For additional information, see *http://www.knownet.hhs.gov/acquisition/careerhandbookver.1.0.doc.*

301.603–73 Earned value training requirement for Contracting Officers/Contract Specialists who administer an IT contract.

All GS–1102s who administer an IT contract, regardless of dollar threshold, are required to successfully complete the Department's (offered through HHS University) one-day course entitled ''Early Warning Project Management Systems Workshop,'' or an equivalent Earned Value training course. Determination of course equivalency shall be made jointly by the Office of Acquisition Management and Policy/ASAM and the HHS Office of the Chief Information Officer.

301.603–74 Training policy exception.

In the event there is an urgent requirement for a Contracting Officer/Contract Specialist to award or administer an IT contract, and the Earned Value training requirement has not been met, the HCA (not delegable) may waive the training requirement and authorize the individual to perform the job duties, provided that the individual attends the next scheduled ''Early Warning Project Management System Workshop'' course, or an equivalent Earned Value course.

301.603–75 Training requirement for purchase cardholders, Approving Officials (AOs), and Agency/Organization Program Coordinators (A/OPCs).

Training requirements for purchase cardholders, AOs, and A/OPCs are listed in the following table:

Authority [a]	Program participant	Required training [b]
Up to $2,500	Prospective/newly appointed purchase cardholders and Approving Officials.	Basic purchase card course (HHS University 1-day course) or an equivalent course that has been approved by the HHS Acquisition Training Coordinator prior to appointment. Training will include green-purchasing and Section 508 requirements.
	Purchase card holders and Approving Officials.	Refresher purchase card training, including green-purchasing training and Section 508 training, every 2 years.
$2,501 to $25,000	Prospective/newly appointed purchase cardholders and Approving Officials.	• Basic Purchase Card course. • Basic Simplified Acquisition Procedures/DAU's CON 237. • Advanced Simplified Acquisition Procedures or Appropriations Law.
	Purchase card holders and Approving Officials.	Refresher purchase card training, including green-purchasing training and Section 508 training, every 2 years.
$25,001 to $100,000	Prospective/newly appointed purchase cardholders and Approving Officials.	• Basic Purchase Card course. • Basic Simplified Acquisition Procedures/DAU's CON 237. • Advanced Simplified Acquisition Procedures or Appropriations Law. • CON 100 (Shaping Smart Business Arrangements). • CON 110 (Mission Support Planning).
	Purchase cardholders and Approving Officials.	Refresher purchase card training, including green-purchasing training and Section 508 training, every 2 years.
Not applicable	Prospective/newly appointed Agency/Organization Program Coordinators.	Basic Purchase Card course, Basic Simplified Acquisition Procedures or DAU's CON 237, Advanced Simplified Acquisition Procedures or Appropriations Law, CON 100 (Shaping Smart Business Arrangements), and CON 110 (Mission Support Planning).
	Agency/Organization Program Coordinators.	Refresher purchase card training, including green-purchasing training and Section 508 training, every 2 years (attendance at GSA's annual training conference satisfies refresher training).

[a] Cardholders and Approving Officials with authorized increases in DPA have up to 6 months to complete the training requirements for the new DPA.

[b] CON 237, CON 100, and CON 110 are available at the DAU Web site at *http://www.dau.mil/registrar/enroll.asp*. CON 100 is also offered through HHS University (see Web site at: *http://learning.hhs.gov*).

301.603–76 Requirement for certification retention and maintaining currency of acquisition knowledge and skills for Contracting Officers/Contract Specialists and purchasing agents.

To maintain a FAC–C, GS–1102s, including all warranted Contracting Officers regardless of series, shall earn 80 continuous learning points (CLPs) every two years beginning January 1, 2008. For GS–1105s and GS–1106s, a minimum of forty (40) hours (or continuous learning points) is required every two years after all mandatory training requirements have been met. Certification will expire if the CLPs are not earned every two years, and may result in a loss of warrant authority.

PART 302—DEFINITIONS OF WORDS AND TERMS

■ 14. Revise section 302.101 to read as follows:

302.101 Definitions.

Agency head or *head of the Agency*, unless otherwise specified, means the head of the Operating Division (OPDIV) for Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Substance Abuse and Mental Health Services (SAMHSA), and the Deputy Secretary for the Office of the Secretary (OS).

Chief of the Contracting Office (CCO) is typically a mid-level management official, usually an office director, division director, or branch chief, who manages and monitors the daily contract operations of an OPDIV or major component of an OPDIV. The CCO is subordinate to the Head of Contracting

Activity (HCA), except where the HCA and CCO are the same individual.

Head of the contracting activity (HCA)—

(1) Occupies designated organization positions as follows:

ASAM–OS—Deputy Assistant Secretary for Acquisition Management and Policy

AHRQ—Director, Division of Contracts Management

CMS—Director, Office of Acquisition and Grants Management

PSC—Director, Division of Acquisition Management

CDC—Director, Procurement and Grants Office

FDA—Director, Office of Acquisitions & Grant Services

HRSA—Director, Division of Procurement Management

IHS—Director, Division of Acquisition Policy

NIH—Director, Office of Acquisition Management and Policy

SAMHSA—Director, Division of Contracts Management

(2) Each HCA is responsible for conducting an effective and efficient acquisition program. Adequate controls shall be established to assure compliance with applicable laws, regulations, procedures, and the dictates of good management practices. Periodic reviews shall be conducted and evaluated by qualified personnel, preferably assigned to positions other than in the contracting office being reviewed, to determine the extent of adherence to prescribed policies and regulations, and to detect a need for guidance and/or training.

(3) The heads of contracting activities may redelegate their HCA authorities to the extent that redelegation is not prohibited by the terms of their respective delegations of authority, by law, by the Federal Acquisition Regulation, by the HHS Acquisition Regulation, or by other regulations. However, HCA and other contracting approvals and authorities shall not be redelegated below the levels specified in the HHS Acquisition Regulation or, in the absence of coverage in the HHS Acquisition Regulation, the Federal Acquisition Regulation. To ensure proper control of redelegated acquisition authorities, HCAs shall maintain a file containing successive delegations of HCA authority through and including the Contracting Officer level. Personnel delegated responsibility for acquisition functions must possess a level of experience, training, and ability commensurate with the complexity and magnitude of the acquisition actions involved.

Project Officer is a Federal employee who monitors contractor performance and provides technical guidance to the Contract Specialist/Contracting Officer. The Project Officer serves as the Contract Specialist/Contracting Officer's authorized representative to monitor specific aspects of the contract, thereby ensuring that the contractor's performance meets the standards set forth in the contract, the technical requirements under the contract are met by the delivery date(s) and/or within the period of performance, and performance is accomplished within the price or estimated cost stated in the contract. A Project Officer is required to comply with HHS Project Management Certification Program training requirements. The term ''Project Officer'' is synonymous with Contracting Officer's Representative (COR) and Contracting Officer's Technical Representative (COTR).

■ 15. Revise section 302.201 to read as follows:

302.201 Contract clause.

The FAR clause, Definitions, at 52.202–1 shall be used as prescribed in FAR 2.201, except as follows:

(a) In accordance with 52.202–1(a)(1), paragraph (a) at 352.202–1 shall be used in place of paragraph (a) of the FAR clause.

(b) In accordance with 52.202–1(a)(1), paragraph (h), or its alternate, at 352.202–1 shall be added to the end of the FAR clause. Use paragraph (h) when a fixed-priced contract is anticipated; use the alternate to paragraph (h) when a cost-reimbursement contract is anticipated. This is an authorized deviation.

PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

■ 16. Revise section 303.101–3 to read as follows:

303.101–3 Agency regulations.

(a)(3) The Department of Health and Human Services' Standards of Conduct are prescribed in 45 CFR part 73.

■ 17. Revise paragraph (a)(2)(i) of section 303.104–7 to read as follows:

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

(a) * * *

(2) * * *

(i) Refer the matter immediately to the Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP), Assistant Secretary for Administration and Management, Office of the Secretary, for review, which may consult with the Office of General Counsel (OGC) and the Office of Inspector General (OIG), as appropriate; and

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■ 18. Revise section 303.303 to read as follows:

303.303 Reporting suspected antitrust violations.

(h) A copy of the agency report of suspected antitrust violations submitted to the Attorney General by the HCA shall also be submitted to the Director, Office of Acquisition Management and Policy.

■ 19. Revise section 303.405 to read as follows:

303.405 Misrepresentations or violations of the Covenant Against Contingent Fees.

(a) Reports shall be made promptly to the Contracting Officer.

(b)(4) Suspected fraudulent or criminal matters to be reported to the Department of Justice shall be prepared in letter format and forwarded through acquisition channels to the head of the contracting activity for signature. The letter must contain all pertinent facts and background information considered by the Contracting Officer and chief of the contracting office that led to the decision that fraudulent or criminal matters may be present. A copy of the signed letter shall be sent to the Director, Office of Acquisition Management and Policy.

■ 20. Revise section 303.704 to read as follows:

303.704 Policy.

(a) For purposes of implementing FAR subpart 3.7, the authorities granted to the ''agency head or designee'' shall be exercised by the HCA (not delegable).

PART 304—ADMINISTRATIVE MATTERS

■ 21. Revise section 304.602 to read as follows:

304.602 Federal Procurement Data System—Next Generation (FPDS–NG).

The Departmental Contracts Information System (DCIS) represents the Department's implementation of the FPDS-NG. All departmental contracting activities are required to use the DCIS and follow the procedures stated in the Enhanced Departmental Contracts Information System Manual, available at *http://dcis.hhs.gov*, and amendments to the manual. The HCA (not delegable) shall ensure that all required contract information is collected, submitted, and received into the DCIS on or before the 15th of each month for all contracts and

contract modifications awarded in the previous month.

■ 22. Amend 304.804–70 by revising paragraphs (a) and (b)(1) to read as follows:

304.804–70 Contract closeout audits.

(a) Contracting Officers shall rely, to the maximum extent possible, on single audits to close physically completed cost-reimbursement contracts with colleges and universities, hospitals, non-profit firms, and State and local governments. In addition, where appropriate, a sample of these contractors may be selected for audit, in accordance with paragraph (b) of this section.

(b) * * *

(1) The Office of the Inspector General (OIG) and ASAM's Deputy Assistant Secretary for Acquisition Management and Policy in conjunction with the OPDIV's cost advisory/audit focal point, determine which contracts or contractors will be audited, which audit agency will perform the audit, and the type and scope of closeout audit to be performed. These decisions shall be based upon the needs of the customer, risk analysis, return on investment, and the availability of audit resources. When an audit is warranted prior to closing a contract, the Contracting Officer shall submit the audit request to the OIG's Office of Audit, via the OPDIV's cost advisory/audit focal point.

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■ 23. Revise paragraphs (b)(3), (b)(6), and (e) of section 304.7001 to read as follows:

304.7001 Numbering acquisitions.

* * * * *

(b) * * *

(3) The three digit numeric identification code assigned by the Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP) to the contracting office within the servicing agency;

* * * * *

(6) A one digit code describing the type of contract action:

A Commercial Item Acquisition
C New Definitive Contract
P Purchase Using Simplified Acquisition
I Indefinite Delivery Contract (IDIQ)
O Basic Ordering Agreement (BOA)
B Blanket Purchase Agreement (BPA)
F Facilities Contract
U Contracts placed with or through other Government departments, GSA contracts, or against mandatory source contracts such as the National Industries for the Blind (NIB), the National Industries for the Severely Handicapped (NISH), and the Federal Prison Industries (UNICOR)
L Lease Agreement
W Government-wide Acquisition Contract (GWAC)
E Letter Contract
G Federal Supply Schedule
M Micropurchase

For example, the first contract for NIH, National Cancer Institute, for fiscal year 2005 may be numbered HHSN261200500001C.

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(e) *Assignment of identification codes.* Each contracting office of the Department shall be assigned a three digit identification code by the ASAM/OAMP. Requests for the assignment of codes for newly established contracting offices shall be submitted by a headquarters official from the new contracting office to the OAMP. A listing of the contracting office identification codes currently in use is contained in the Enhanced Departmental Contracts Information System Manual, available at *http://dcis.hhs.gov.*

PART 305—PUBLICIZING CONTRACT ACTIONS

■ 24. Revise section 305.202 to read as follows:

305.202 Exceptions.

(b) When a contracting office believes that it has a situation where advance notice is not appropriate or reasonable, it shall prepare a memorandum citing all pertinent facts and details and send it, through normal acquisition channels, to the Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP) requesting relief from synopsizing. The DASAMP shall review the request and decide whether an exception to synopsizing is appropriate or reasonable. If it is, the DASAMP shall take the necessary coordinating actions required by FAR 5.202(b). Whatever the decision is on the request, the DSAMP shall promptly notify the contracting office when a determination has been made.

■ 25. Revise section 305.303 to read as follows:

305.303 Announcement of contract awards.

(a) *Public announcement.* Awards over $3.5 million, not otherwise exempt under FAR 5.303, shall be reported by the Contracting Officer to the Office of the Assistant Secretary for Legislation (Congressional Liaison), Room 406G, Hubert H. Humphrey Building. Notification shall be accomplished by providing a copy of the contract or award document face page to the referenced office prior to the day of award, or in sufficient time to allow for an announcement to be made by 5 p.m. Washington, DC time on the day of award. Notification may also be accomplished by e-mailing a copy of the contract or award document face page to *grantfax@hhs.gov,* or faxing to (202) 205–2420.

■ 26. Revise section 305.502 to read as follows:

305.502 Authority.

The Contracting Officer may advertise or place notices in newspapers and periodicals to announce that proposals are being sought.

PART 306—COMPETITION REQUIREMENTS

■ 27. Revise section 306.302–1 to read as follows:

306.302–1 Only one responsible source and no other supplies or services will satisfy agency requirements.

(a)(2)(iv) Follow-on contracts for the continuation of major research and development studies on long-term social and health programs, major research studies, or clinical trials may be deemed to be available only from the original source when it is likely that award to any other source would result in unacceptable delays in fulfilling the Department's or OPDIV's requirements.

(b) *Application.* (5) When the head of the program office has determined that only specified makes and models of technical equipment or parts must be obtained to meet the activity's program responsibility to test and evaluate certain kinds and types of products, and only one source is available. (This criterion is limited to testing and evaluation purposes only and may not be used for initial outfitting or repetitive acquisitions. Project officers should support the use of this criterion with citations from their agency's legislation and the technical rationale for the item of equipment required.)

■ 28. Revise section 306.303–1 to read as follows:

306.303–1 Requirements.

(a)(1) The Program Office must provide a written justification whenever it requests that certain goods or services be obtained without full and open competition. The justification must explain why full and open competition is not feasible and must be submitted with the requisition or request for contract.

(i) Justifications in excess of the simplified acquisition threshold shall be in the form of a separate, self-contained

document, prepared in accordance with FAR 6.303 and 306.303, and called a ''JOFOC'' (Justification for Other Than Full and Open Competition). Justifications at or below the simplified acquisition threshold may be in the form of a paragraph or paragraphs contained in the requisition or request for contract.

(ii) Justifications, whether over or under the simplified acquisition threshold, shall fully describe what is to be acquired, offer reasons which go beyond inconvenience, and explain why it is not feasible to obtain competition. The justifications shall be supported by verifiable facts rather than mere opinions. Documentation in the justification should be sufficient to permit an individual with technical competence in the area to follow the rationale.

(iii) Sole source justifications using the Federal Supply Schedule shall include the content listed in FAR 6.303–2.

(b) Preliminary arrangements or agreements with the proposed contractor shall have no effect on the rationale used to support an acquisition for other than full and open competition.

■ 29. Revise section 306.303–2 to read as follows:

306.303–2 Content.

(a)(1) Each justification shall include the name of the program office; the name, address, and phone number of the Project Officer; and project identification, such as the authorizing program legislation, to include citations or other internal program identification data such as title, contract number, etc.

(2) The description may be in the form of a statement of work, purchase description, or specification. A statement is to be included to explain whether the acquisition is an entity in itself, whether it is one in a series, or part of a related group of acquisitions.

(c) JOFOCs shall be signed by the Project Officer, the Project Officer's immediate supervisor, the Contracting Officer, and the approving official (if the approving official is not the Contracting Officer).

■ 30. Revise section 306.304 to read as follows:

306.304 Approval of the justification.

(a)(2) The competition advocates are listed in 306.501. This authority is not delegable.

(3) The competition advocate shall exercise this approval authority, except where the individual designated as the competition advocate does not meet the requirements of FAR 6.304 (a)(3)(ii). This authority is not delegable.

(4) The senior procurement executive of the Department is the Deputy Assistant Secretary for Acquisition Management and Policy. This designation has been made pursuant to the OFPP Act (41 U.S.C. 414(c)(2)(B).

(c) A class justification shall be processed the same as an individual justification.

■ 31. Revise section 306.501 to read as follows:

306.501 Requirement.

The Department's competition advocate is the Director, Strategic Acquisition Service, Program Support Center (PSC). The competition advocates for each of the Department's contracting activities are as follows:

AHRQ—Director, Office of Performance Accountability, Resources and Technology
CDC—Chief Information Officer
CMS—Chief Operating Officer
FDA—Chief, Office of Shared Services
HRSA—Associate Administrator, Office of Administration and Financial Management
IHS—Director, Office of Management Services
NIH—Senior Scientific Advisor for Extramural Research, Office of Extramural Research (R&D) and Senior Advisor to the Director (Other than R&D)
PSC—Director, Strategic Acquisition Service
SAMHSA—Executive Officer

PART 307—ACQUISITION PLANNING

■ 32. Revise section 307.104 to read as follows:

307.104 General procedures.

(a) Each contracting activity shall prepare an Annual Acquisition Plan (AAP). The AAP is a macro plan, containing a list of anticipated contract actions over the simplified acquisition threshold and their associated funding, as well as the aggregate planned dollars for simplified acquisitions by quarter, developed for each fiscal year. The AAP shall conform to reasonable budget expectations and shall be reviewed at least quarterly and modified as appropriate. The HCA or the CCO shall obtain this information from the program planning/budget office of the contracting activity and use the AAP to provide necessary reports and monitor the workload of the contracting office. For contract actions, the plan shall contain, at a minimum:

(1) A brief description (descriptive title, perhaps one or two sentences if necessary);

(2) Estimated award amount;

(3) Requested award date;

(4) Name and phone number of contact person (usually the Project Officer);

(5) Other information required for OPDIV needs.

(b) Once the AAP is obtained from the program planning/budget office, the Contracting Officer/Contract Specialist shall initiate discussions with the assigned Project Officer for each planned negotiated acquisition over $100,000 except for:

(1) Acquisitions made under interagency agreements, and

(2) Contract modifications which exercise options, make changes authorized by the Changes clause, or add funds to an incrementally funded contract. (The HCA may prescribe procedures for contract actions not covered by this subpart.)

(c) The purpose of the discussions between the Contracting and Project Officers is to develop an individual acquisition planning schedule and to address areas that will need to be covered in the request for contract (RFC), including clearances, acquisition strategy, sources, etc. The Project Officer must either have a statement of work (SOW) ready at this time or must discuss in more detail the nature of the services/supplies that will be required.

(d) Standard lead-times for processing various types of acquisitions and deadlines for submission of acceptable RFCs (that is, RFCs which include all required elements such as clearances, funding documents, and an acceptable SOW) for award in a given fiscal year shall be established by the HCA or designee not lower than the CCO.

(e) The outcome of the discussions referenced in paragraph (c) of this section between the Project Officer and the Contracting Officer/Contract Specialist will be an agreement concerning the dates of significant transaction-specific acquisition milestones, including the date of submission of the RFC to the Contracting Officer. This milestone schedule document will be prepared with those dates and will be signed by the Project Officer and the Contracting Officer. The milestones cannot be revised except by mutual agreement of these same individuals. If the planning schedule indicates the need to obtain approval of a Justification for Other than Full and Open Competition, the HCA or CCO must sign the milestone agreement. This document shall be retained in the contract file. All other considerations that will affect the acquisition (technical, business, management) shall be addressed in the RFC (*see* 307.71).

■ 33. Revise section 307.170 to read as follows:

307.170 Program training requirements.

(a) HHS will maintain a program for certifying employees before they may be considered eligible for appointment as a program/project manager or COR/COTR.

(b) All HHS program/project managers, alternate program/project managers, CORs/COTRs, alternate CORs/COTRs, and at least fifty percent of the HHS program personnel performing the function of technical proposal evaluator on a technical evaluation team or panel for a competitively solicited HHS contract, shall have successfully completed the Department's ''Basic Project Officer'' course, or an equivalent course, before assuming the duties of their designated role, or take the next available class. This requirement applies to the initial technical proposal evaluation and any subsequent technical evaluations that may be required. (*Peer and objective reviewers are excluded from these requirements). Course equivalency for the ''Basic Project Officer'' course will be determined by the ASAM/OAMP. The Contracting Officer is responsible for ensuring that the program/project manager, COR/COTR, and proposal evaluators have successfully completed the required training. Non-information technology (IT) program/project managers and non-IT CORs/COTRs who have successfully completed the appropriate ''Basic Project Officer'' course, or an equivalent course, are highly encouraged to take the Department's one-day course entitled ''Early Warning Project Management System Workshop,'' or an equivalent Earned Value course. Program/Project managers and CORs/COTRs are highly encouraged to take the Department's ''Writing Statements of Work'' course, or an equivalent course. Peer and objective reviewers are excluded from these requirements. (*The peer review process pertains specifically to NIH in the peer review of applications for grants and contracts. Applications are evaluated by a peer review group composed of scientists from the extramural research community.) All courses are offered through HHS University.

■ 34. Revise section 307.170–1 to read as follows:

307.170–1 Training policy exceptions.

In the event there is an urgent requirement for a specific individual to serve as a program/project manager and COR/COTR (or alternate program/project manager and alternate COR/COTR) and that individual has not successfully completed the prerequisite training course(s), the HCA (not delegable) may waive the training requirement and authorize the individual to perform the project duties, provided that:

(a) The individual first meets with the cognizant Contracting Officer to review the HHS ''Project Officer's Contracting Handbook'' to discuss the important aspects of the contracting-program office relationship as appropriate to the circumstances; and

(b) The individual attends the next scheduled ''Basic Project Officer'' course, or an equivalent course, and, for those current and proposed IT program/project managers, as well as alternate IT program/project managers and IT CORs/COTRs (as well as alternate CORs/COTRs) assigned to HHS IT projects (including those designated as major or tactical by HHS), the next ''Early Warning Project Management System Workshop.''

■ 35. Add sections 307.170–3 through 307.170–9 to subpart 307.1 to read as follows:

Subpart 307.1—Acquisition Planning

307.170–3 Earned value training requirement for IT program/project managers and IT CORs/COTRs.
307.170–4 Required training in HHS' portfolio management tool.
307.170–5 Maintenance/refresher training requirement for program/project managers and CORs/COTRs.
307.170–6 Warranting of Other Transaction Officers for Other Transactions.
307.170–7 Training Requirements for Other Transaction Officers.
307.170–8 Appointment of an Other Transaction Officer Technical Representative for an Other Transaction.
307.170–9 Training requirement for an Other Transaction Officer Technical Representative.

Subpart 307.1—Acquisition Planning

* * * * *

307.170–3 Earned value training requirement for IT program/project managers and IT CORs/COTRs.

All current and proposed IT program/project managers, alternate IT program/project managers, IT CORs/COTRs, and alternate CORs/COTRs assigned to HHS IT projects (including those IT projects designated as major or tactical), regardless of dollar threshold, must successfully complete the Department's (offered through HHS University) one-day course entitled ''Early Warning Project Management System Workshop,'' or an equivalent Earned Value training course. Course equivalency will be determined jointly by the ASAM/OAMP and the HHS Office of the Chief Information Officer.

307.170–4 Reqired training in HHS' portfolio management tool.

All current and proposed IT program/project managers, as well as alternate IT program/project managers and IT CORs/COTRs (as well as alternate IT CORs/COTRs), regardless of dollar threshold, must successfully complete training in HHS' portfolio management tool (contact the HHS Office of the Chief Information Officer for additional information).

307.170–5 Maintenance/refresher training requirement for program/project managers and CORs/COTRs.

Program/Project Managers and CORs/COTRs who monitor one or more contracts are required to take 40 CLPs each year.

307.170–6 Warranting of Other Transaction Officers for Other Transactions.

(a) Other Transaction (OT) Officers shall possess the qualifications necessary to ensure that OTs are in compliance with applicable laws and regulations. The ASAM/OAMP will have the sole authority to warrant OT Officers at HHS. To receive a warrant as an HHS OT Officer, the individual must be a Contracting Officer, preferably with an unlimited warrant, with a Federal Acquisition Certification in Contracting (FAC–C) Level III, or a Level III or IV certified Grants Officer within HHS. Nominations for appointment of OT Officers shall be submitted to the Head of Contracting Activity in writing through appropriate organizational channels for review. The nomination package shall include the following:

(1) A completed Appendix A (''OT Officer's Warrant Application Form'') of HHS Other Transaction Authority Guidebook;

(2) A recommendation from the employee's immediate supervisor providing justification for the appointment of an HHS OT Officer;

(3) Current resume/OF 612/SF 171 and/or other documentation describing the employee's experience, education, and training relevant to the position for which warrant authority is being sought;

(4) A copy of the employee's most recent performance appraisal;

(5) Type of work to be performed under the warrant, i.e., executing OTs;

(6) A copy of the certificate issued under the HHS Acquisition Certification Program indicating the employee's current certification level and a copy of previous warrant certificate, if applicable; or a copy of the certificate issued under the HHS Grants Certification Program, if applicable; and

(7) Proof of successful completion of the ''Cooperative Agreements, CRADAs

& Other Transactions'' course taught by Federal Publications Seminars, or an equivalent course.

(b) For additional information, see *http://www.knownet.hhs.gov/acquisition/hhs_epp_postings/HHSGuidebook1-OTAMarch2005.doc.*

307.170–7 Training Requirements for Other Transaction Officers.

OT Officers must successfully complete the ''Cooperative Agreements, CRADAs & Other Transactions'' course, or an equivalent course, prior to appointment as an OT Officer. Grants Officers who serve as OT Officers are required to have successfully completed the following courses: CON 110 (''Mission Support Planning''); CON 111 (''Mission Strategy Execution,''); CON 112 (''Mission Performance,'') or CON 120 (''Mission Focused Contracting.''), or equivalent courses *prior* to being appointed as an OT Officer. The HHS OTA Board will determine course equivalency.

307.170–8 Appointment of an Other Transaction Officer Technical Representative for an Other Transaction.

The program office nominates the Other Transaction Officer Technical Representative (OTR). The OT Officer prepares an OTR delegation memorandum that describes the OTR's authority and assigns the OTR specific responsibilities, with limitations of authority, in writing. The OTR represents the OT Officer only to the extent delegated in the written appointment and does not have the authority to change the terms and conditions of the OT.

307.170–9 Training requirement for an Other Transaction Officer Technical Representative.

(a) Program personnel selected to serve as an OTR or an alternate OTR assigned to an OT, and at least fifty percent of the technical evaluators that review the initial and any subsequent proposals or revisions thereof, shall successfully complete the Department's ''Basic Project Officer'' course, or an equivalent course prior to being appointed. Determination of course equivalency shall be made by the HHS OTA Board.

(b) In addition to the Department's required ''Basic Project Officer'' course, the OTR or alternate OTR assigned to an OT, and at least fifty percent of the technical evaluators that review the initial and any subsequent proposals or revisions thereof, shall successfully complete the ''Cooperative Agreements, CRADAs & Other Transactions'' course, or an equivalent course, prior to being appointed and prior to assuming job duties associated with the OT.

(c) Refresher training in the policies and procedures of awarding cooperative agreements, CRADAs and OTs is required every three years.

307.302, 307.303, 307.304, and 307.307 [Removed]

■ 36. Remove subpart 307.3 (sections 307.302, 307.303, 307.304, and 307.307).

■ 37. Revise paragraph (b)(2) of section 307.7001 to read as follows:

307.7001 Distinction between acquisition and assistance.

* * * * *

(b) * * *

(2) The Department determines in a specific instance that the use of a type of contract is appropriate. That is, it is determined in a certain situation that specific needs can be satisfied best by using the acquisition process. However, this authority does not permit circumventing the criteria for use of acquisition or assistance instruments. Use of this authority is restricted to extraordinary circumstances and only with the prior approval of the Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP).

* * * * *

■ 38. Revise section 307.7104 to read as follows:

307.7104 Transmittal.

The RFC must be conveyed to the contracting office by use of a cover memorandum. The cover memorandum must be signed by the head of the sponsoring program office and include both a statement attesting to the conclusiveness of the review described in 307.7103(b) and a list identifying all attachments to the RFC.

■ 39. Amend section 307.7105 by revising the introductory text for the section, the introductory text for paragraph (b)(4), and paragraphs (b)(4)(i) and (b)(7) to read as follows:

307.7105 Format and content.

The Department is in the process of standardizing a format for the RFC. In the interim, the information in paragraph (a) of this section must be included. Paragraph (b) contains information that must also be included if applicable.

* * * * *

(b) * * *

(4) *Special program clearances or approvals.* The following special program clearances or approvals should be reviewed for applicability to each acquisition. Those which are applicable should be addressed during the planning discussions between the Project Officer and Contracting Officer/Contract Specialist (see 307.104(c)) and immediate action should be initiated by the Project Officer to obtain the necessary clearances or approvals. The Contracting Officer/Contract Specialist shall provide a comprehensive checklist of these and any OPDIV special approvals, clearances, and requirements to the program office. If the approval or clearance has been requested and is being processed at the time of RFC submission, a footnote to this effect, including all pertinent details, must be included in this section.

(i) *Commercial activities.* (OMB Circular No. A–76). An RFC must contain a statement as to whether the proposed solicitation is or is not to be used as part of an OMB Circular No. A–76 public-private cost comparison. (See OMB Circular No. A–76, Performance of Commercial Activities.)

* * * * *

(7) *Special terms and conditions.* Any suggested special terms and conditions not already covered in the statement of work.

* * * * *

■ 40. Amend section 307.7106 by revising paragraphs (a) and (d) to read as follows:

307.7106 Statement of work.

(a) *General.* A statement of work (SOW) describes the work or services to be performed in reaching an end result without describing the method that will be used unless the method of performance is critical or required in order to obtain successful performance. The SOW should be clear and concise and must completely define the responsibilities of both the contractor and the Government. The SOW should be worded to make more than one interpretation virtually impossible.

* * * * *

(d) *Elements of the SOW.* The elements of the SOW will vary with the objective, complexity, size, and nature of the acquisition. In general, it should include the following:

(1) *Purpose of the project.* This includes a general description of the objectives of the project and the desired results.

(2) *Background information.* This includes a brief history of the project and the importance of the project to the overall program objectives.

(3) *A detailed description of the technical requirements.* The statement of work should provide sufficient detail to accurately reflect the Government's requirement. It should state what is to

be done without prescribing the method to be used and should include performance standards. The statement of work may be broken down into tasks and subtasks. The degree of breakout depends on the size and complexity of the project. The statement of work should indicate whether the tasks are sequential or concurrent.

(4) *Reference material.* All reference material to be used in the conduct of the project that indicates how the work is to be carried out must be identified. Applicability should be explained, and a statement made as to where the material can be obtained.

(5) *Level of effort.* When a level of effort is required, the number and type of personnel required should be stated. If known, the type and degree of expertise should be specified.

(6) *Special requirements.* (as applicable). An unusual or special contractual requirement, which would impact on contract performance, should be included as a separate section.

(7) *Deliverables reporting requirements.* All deliverables and/or reports must be clearly and completely described. Include the timeframe for completion, the format, and the number of copies.

PART 309—CONTRACTOR QUALIFICATIONS

■ 41. Revise section 309.403 to read as follows:

309.403 Definitions.

Acquiring agency's head or designee, as used in the FAR, shall mean, unless otherwise stated in this subpart, the head of the contracting activity. Acting in the capacity of the acquiring agency's head, the head of the contracting activity may make the required justifications or determinations, and take the necessary actions, specified in FAR 9.405, 9.406, and 9.407 for his or her respective activity, but only after obtaining the written approval of the debarring or suspending official, as the case may be.

Debarring official means the Assistant Secretary for Administration and Management, or his/her designee.

Initiating official means either the contracting officer, the head of the contracting activity, the Deputy Assistant Secretary for Acquisition Management and Policy, or the Inspector General.

Suspending official means the Assistant Secretary for Administration and Management, or his/her designee.

■ 42. Revise section 309.404 to read as follows:

309.404 List of parties excluded from Federal procurement and nonprocurement programs.

(c) The Office of Acquisition Management and Policy (OAMP) shall perform the actions required by FAR 9.404(c).

(4) OAMP shall maintain all documentation submitted by the initiating official recommending the debarment or suspension action and all correspondence and other pertinent documentation generated during the OAMP review.

■ 43. Amend section 309.405 by revising paragraph (a)(1) to read as follows:

309.405 Effect of listing.

(a) * * *

(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 acquisition channels to the head of the contracting activity. The documentation must 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:

(i) The property or services to be acquired are available only from the listed contractor; or

(ii) The urgency of the requirement dictates that the Department conduct business with the listed contractor.

* * * * *

■ 44. Revise section 309.406–3 to read as follows:

309.406–3 Procedures.

(a) *Investigation and referral.* When an apparent cause for debarment becomes known, the initiating official shall prepare a report containing the information required by 309.470–2, along with a written recommendation, and forward it through appropriate channels to the debarring official. Reports shall be forwarded in accordance with 309.470–1. The debarring official, the Deputy Assistant Secretary for Acquisition Management and Policy, shall initiate an investigation.

(b) *Decision making process.* The debarring official shall review the results of the investigation, if any, and make a written determination whether or not debarment procedures are to be commenced. A copy of the determination shall be promptly sent through appropriate channels to the initiating official and the Contracting Officer. If it is determined that debarment procedures shall commence, the debarring official shall consult with the Office of General Counsel and then notify the contractor in accordance with FAR 9.406–3(c). If the proposed action is not based on a conviction or judgment and the contractor's submission in response to the notice raises a genuine dispute over facts material to the proposed debarment, the debarring official shall arrange for fact-finding hearings and take the necessary action specified in FAR 9.406–3(b)(2). The debarring official shall also ensure that written findings of facts are prepared, and shall base the debarment decisions on the facts as found, after considering information and argument submitted by the contractor and any other information in the administrative record. The Office of the General Counsel shall represent the Department at any fact-finding hearing and may present witnesses for HHS and question any witnesses presented by the contractor.

■ 45. Revise section 309.407–3 to read as follows:

309.407–3 Procedures.

(a) *Investigation and referral.* When an apparent cause for suspension becomes known, the initiating official shall prepare a report containing the information required by 309.470–2 along with a written recommendation and forward it through appropriate channels to the suspending official. Reports shall be forwarded in accordance with 309.470–1. The suspending official shall initiate an investigation.

(b) *Decision making process.* The suspending official shall review the results of the investigation, if any, and make a written determination whether or not suspension should be imposed. A copy of this determination shall be promptly sent through appropriate channels to the initiating official and the Contracting Officer. If it is determined that suspension shall be imposed, the suspending official shall consult with the Office of General Counsel and then notify the contractor in accordance with FAR 9.407–3(c). If the action is not based on an indictment, and, subject to the provisions of FAR 9.407–3(b)(2), the contractor's submission in response to the notice raises a genuine dispute over facts material to the suspension, the suspending official shall, after suspension has been imposed, arrange for fact-finding hearings and take the necessary actions specified in FAR 9.407–3(b)(2).

■ 46. Amend section 309.470–1 by revising the introductory text to read as follows:

309.470–1 Situations where reports are required.

A report incorporating the information required by 309.470–2 shall be forwarded, in duplicate, by the Contracting Officer through acquisition channels to OAMP when:

* * * * *

■ 47. Add part 311 to read as follows:

PART 311—DESCRIBING AGENCY NEEDS

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

311.003 Defining Electronic Information Technology (EIT) requirements.

HHS officials who are defining agency needs for EIT products and services and performing market research to meet those needs can use the Buy Accessible Wizard (*http://www.buyaccessible.gov*) managed by the General Services Administration to document EIT requirements, identify the applicable Section 508 standards, and document the market research.

■ 48. Add part 312 to read as follows:

PART 312—ACQUISITION OF COMMERCIAL ITEMS

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 312.1—Acquisition of Commercial Items—General

312.101 Policy.

(a) It is HHS policy to maximize its buying power, reduce acquisition administrative costs, and develop long-term, mutually beneficial, open partnerships with best-in-class providers of products and services. Accordingly, HHS has implemented a Strategic Sourcing Program under which Indefinite-Delivery/Indefinite-Quantity contracts (IDIQs) and Blanket Purchase Agreements (BPAs), known as HHS-wide Acquisition Contracts (HWACs), are awarded to allow for savings for commercial items and services across HHS and make the acquisition process more efficient.

(b) If consideration is being given to soliciting or acquiring a product or service from a source, other than HHS Contract Closeout IDIQs or Strategic Sourcing BPAs, when the category of the current requirement (e.g. Lab Supplies, Events Management) is encompassed in the portfolio of existing IDIQ or BPA categories a waiver request must be prepared and approved in advance of a purchase or processing of a requirement.

(c) The instructions, including approval requirements, and waiver form, are available at *http://dbh.ogam2000.com/HHS_Strategic_Sourcing/Data_Collection/waiver.asp*.

The following links provide more detailed information regarding the supplies, equipment, and services in each of the HWACs: the HHS Acquisition Integration and Modernization Web site: *http://intranet.hhs.gov/hwac/index.html* and the HHS Strategic Sourcing Web site: *http://intranet.hhs.gov/ssc/*.

PART 314—SEALED BIDDING

■ 49. Revise section 314.202–7 to read as follows:

314.202–7 Facsimile bids.

(c) If the HCA (not delegable) has determined that the contracting activity will allow use of facsimile bids and proposals, the HCA shall prescribe internal procedures, in accordance with the FAR, to ensure uniform processing and control.

314.213 [Removed]

■ 50. Remove section 314.213.

■ 51. Revise section 314.404–1 to read as follows:

314.404–1 Cancellation of invitations after opening.

(c) The HCA or CCO (not delegable) shall make the determinations required to be made by the agency head in FAR 14.404–1.

■ 52. Revise section 314.407–3 to read as follows:

314.407–3 Other mistakes disclosed before award.

(e) Authority has been delegated to the Departmental Protest Control Officer, Office of Acquisition Management and Policy, to make administrative determinations in connection with mistakes in bid alleged after opening and before award. This authority may not be redelegated.

(f) Each proposed determination shall have the concurrence of the Chief, General Law Division, Office of General Counsel.

(i) Doubtful cases shall not be submitted by the Contracting Officer directly to the Comptroller General, but, instead, shall be submitted to the Departmental Protest Control Officer.

■ 53. Amend section 314.407–4 by revising paragraph (d) to read as follows:

314.407–4 Mistakes after award.

* * * * *

(d) Each proposed determination shall have the concurrence of the Chief, General Law Division, Office of General Counsel.

PART 315—CONTRACTING BY NEGOTIATION

■ 54. Add section 315.204–1 to read as follows:

315.204–1 Uniform contract format.

(a) When preparing solicitations and resulting contracts, Contracting Officers/Contract Specialists are strongly encouraged to use as a guide the HHS Solicitation/Contract Structure Document found at *http://www.knownet.hhs.gov/acquisition/policy.htm*.

315.204–5 [Removed]

■ 55. Remove section 315.204–5.

315.209 [Amended]

■ 56. Amend section 315.209 by removing paragraph (g).

■ 57. Amend section 315.305 by revising paragraphs (a)(1), (a)(3)(i)(D), (a)(3)(ii)(B), the introductory text of (a)(3)(ii)(E)(*1*), (a)(3)(ii)(E)(*4*), (a)(3)(ii)(F)(*2*), and (a)(3)(ii)(F)(*3*) to read as follows:

315.305 Proposal evaluation.

(a)(1) *Cost or price evaluation.* (i) The Contracting Officer shall evaluate business proposals in accordance with the requirements set forth in FAR 15.404. The extent of cost or price analysis in each case depends on the contract type, the amount of the proposal, the technical complexity, and related cost or price. The Project Officer shall be requested to analyze the following elements, if applicable, to determine if they are necessary and reasonable for efficient contract performance:

(A) The number of labor hours proposed for the various labor categories and the mix in relation to the technical requirements;

(B) Types, numbers and hours/days of proposed consultants;

(C) The kinds and quantities of material, equipment, supplies, and services;

(D) Kinds and quantities of information technology;

(E) Logic of proposed subcontracting; and

(F) Travel proposed, including number of trips, locations, purpose, and travelers.

(ii) The Project Officer shall provide written comments, including the rationale for any exceptions to the elements. The Project Officer's

comments shall be used for negotiations or to support award without discussions. The Contracting Officer should also request assistance of a cost/price analyst, when necessary. The Contracting Officer's negotiation memorandum must include the rationale used in determining that the price or cost is fair and reasonable.

* * * * *

(3) *Technical evaluation.*

(i) * * *

(D) The technical evaluation plan shall be submitted to the Contracting Officer for review and approval before the solicitation is issued. The Contracting Officer shall make sure that the significant factors and subfactors relating to the evaluation are reflected in the evaluation criteria when conducting the review of the plan.

(ii) * * *

(B) *Role of the Project Officer.* (*1*) The Project Officer is the Contracting Officer's technical representative for the acquisition action. The Project Officer may be a voting member of the technical evaluation panel, and may also serve as the chairperson of the panel, unless prohibited by law or contracting activity procedures.

(*2*) The Project Officer is responsible for recommending panel members who are knowledgeable in the technical aspects of the acquisition and capable of identifying strengths and weaknesses in the proposals received. Government employees serving as panel members must be selected in accordance with the requirements set forth in 307.170.

(*3*) The Project Officer shall ensure that persons possessing expertise and experience in addressing issues relative to sex, race, national origin, and handicapped discrimination are included as panel members for acquisitions in which such issues are applicable.

(*4*) The Project Officer shall submit the list of recommended panel members to an official within the project office in a position at least one level higher. This official will review the list and select the chairperson.

(*5*) The Project Officer shall arrange for adequate and secure working space for the panel.

* * * * *

(E) *Continuity of evaluation process.* (*1*) The technical evaluation panel shall evaluate all original proposals, make recommendations to the chairperson regarding strengths and weaknesses of proposals, and, if required by the Contracting Officer, assist the Contracting Officer during communications and discussions, and review supplemental, revised and/or final proposal revisions. To the extent possible, the same evaluators should be available throughout the entire evaluation and selection process to ensure continuity and consistency in the treatment of proposals. The following are examples of circumstances when it would not be necessary for the technical evaluation panel to evaluate revised proposals submitted during the acquisition:

* * * * *

(*4*) When continuity of the evaluation process is not possible, and either new evaluators are selected or the size of the evaluation panel is reduced, all proposals shall be reviewed by each panel member at the current stage of the acquisition (i.e., initial proposal, final proposal revisions, etc.). Also, guidance should be provided concerning what to do if an unusually large number of proposals are received, including how to determine what constitutes an unusually large number of proposals.

(F) * * *

(*2*) Decisions to disclose proposals to evaluators outside of the Government shall be made by the official responsible for appointing panel members in accordance with operating division procedures. The avoidance of organization conflict of interest and competitive relationships must be taken into consideration when making the decision to use outside evaluators.

(*3*) When it is determined to disclose a solicited proposal outside the Government for evaluation purposes, the following or similar conditions shall be included in the written agreement with evaluator(s) prior to disclosure:

Conditions for Evaluating Proposals

The evaluator agrees to 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 the Department or the submitter of the proposal 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 Departmental office which initially furnished the proposal for evaluation.

Unless authorized by the Department's initiating office, the evaluator shall not contact the submitter of the proposal concerning any aspects of its contents.

The evaluator's employees and subcontractors shall abide by these conditions.

* * * * *

■ 58. Amend section 315.371 by revising the introductory text of paragraph (a) to read as follows:

315.371 Contract preparation and award.

(a) After details have been finalized with the selected offeror, the Contracting Officer shall:

* * * * *

■ 59. Amend section 315.372 by revising the introductory text and paragraph (a) to read as follows:

315.372 Preparation of negotiation memorandum.

The negotiation memorandum or summary of negotiations is a complete record of all actions leading to award of a contract and is prepared by the Contracting Officer/Contract Specialist to support the source selection decision discussed in FAR 15.308. It should be in sufficient detail to explain and support the rationale, judgments, and authorities upon which all actions were predicated. The memorandum will document the negotiation process and reflect the negotiator's actions, skills, and judgments in concluding a satisfactory agreement for the Government. The negotiation memorandum shall address each item listed below. If an item is not applicable, it shall be so stated in the memorandum. Information already contained in the contract file may be referenced rather than reiterated.

(a) *Description of articles and services and period of performance.* A description of articles and services, quantity, unit price, total contract amount, and period of contract performance should be set forth.

* * * * *

■ 60. Amend section 315.404–4 by revising paragraphs (b)(1), the introductory text of (b)(1)(ii), (c), (d)(1)(i), (d)(1)(ii), the introductory text of (d)(1)(iv), and (d)(3)(iv) to read as follows:

315.404–4 Profit.

(b) *Policy.* (1) The structured approach for determining profit or fee (hereafter called profit) provides a technique for establishing a profit objective for negotiation. A profit objective is that part of the estimated contract price objective or value which, in the judgment of the Contracting Officer, constitutes an appropriate amount of profit for the acquisition being considered. This technique allows for consideration of the profit factors described in paragraph (d) of this section. The Contracting Officer's analysis of these factors is based on available information such as proposals, audit data, assessment reports, preaward

surveys, etc. The structured approach provides a basis for documenting the profit objective. Any significant departure from this objective shall be explained. The amount of documentation depends on the dollar value and complexity of the proposed acquisition. The profit objective is a part of the overall negotiation objective and is directly related to the cost objective and any proposed sharing arrangement. The profit objective should be negotiated at the same time as the other cost items. The profit objective should be negotiated as a whole and not as individual profit factors.

(ii) The profit analysis factors in FAR 15.404–4(d) shall be used in lieu of the structured approach in the following circumstances. Factors considered inapplicable to the acquisition shall be excluded from the profit objective. Documentation shall be provided which includes the profit factor breakdown.

* * * * *

(c) *Contracting Officer responsibilities.* The Contracting Officer shall develop the profit objective. This objective shall realistically reflect the total overall task to be performed and the requirements placed on the contractor. The Contracting Officer shall not begin to develop the profit objective until a thorough review of proposed contract work has been made; a review of all available knowledge regarding the contractor pursuant to FAR subpart 9.1, including audit data, preaward survey reports and financial statements, as appropriate, has been conducted; and an analysis of the contractor's cost estimate and comparison with the Government's estimate or projection of cost has been made.

(d) * * *

(1) * * *

(i) The Contracting Officer shall measure ''Contractor Effort'' by assigning a profit percentage within the designated weight range to each element of contract cost. The categories listed are for reference purposes only, but are broad and basic enough to provide guidance to other elements of cost. Facilities capital cost of money is not to be included. A total dollar profit shall be computed for ''Contractor Effort.''

(ii) The Contracting Officer shall use the total dollar profit for the ''Contractor Effort'' to calculate specific profit dollars for ''Other Factors''—cost risk, investment, performance, socioeconomic programs, and special situations. The Contracting Officer shall multiply the total dollar profit for the ''Contractor Effort'' by the weight assigned to each of the elements in the ''Other Factors'' category. Facilities capital cost of money is not included. Form HHS–674, Structured Approach Profit/Fee Objective, should be used. Form HHS–674 is illustrated in 353.370–674.

* * * * *

(iv) The structured approach was designed for arriving at profit objectives for other than nonprofit organizations. However, the structured approach can be used for nonprofit organizations if appropriate adjustments are made. The Contracting Officer shall use the modified structured approach in paragraph (d)(1)(iv)(B) of this section to establish profit objectives for nonprofit organizations.

* * * * *

(3) * * *

(iv) *Federal socioeconomic programs.* This factor, which may apply to special circumstances or particular acquisitions, relates to the extent of a contractor's successful participation in Government sponsored programs such as small business, small disadvantaged business, women-owned small business, service-disabled veterans, handicapped sheltered workshops, and energy conservation efforts. The contractor's policies and procedures which energetically support Government socioeconomic programs and achieve successful results should be given positive considerations. Conversely, failure or unwillingness on the part of the contractor to support Government socioeconomic programs should be viewed as evidence of poor performance for the purpose of establishing a profit objective.

* * * * *

■ 61. Amend section 315.606 by revising paragraph (b) to read as follows:

315.606 Agency procedures.

* * * * *

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

■ 62. Amend section 315.609 by revising the introductory text to read as follows:

315.609 Limited use of data.

The legend, Use and Disclosure of Data, prescribed in FAR 15.609(a) is to be used by the offeror to restrict the use of data for evaluation purposes only. However, data contained within the unsolicited proposal may have to be disclosed as a result of a request submitted pursuant to the Freedom of Information Act. Because of this possibility, the following notice shall be provided to all prospective offerors of unsolicited proposals:

* * * * *

PART 316—TYPES OF CONTRACTS

■ 63. Add section 316.505 to read as follows:

316.505 Ordering.

(b)(5) The Department's task-order and delivery-order ombudsman is the Director, Strategic Acquisition Service, Program Support Center (PSC). The task-order and delivery-order ombudsmen for each of the Department's contracting activities are as follows:

AHRQ—Director, Office of Performance Accountability, Resources and Technology
CDC—Chief Information Officer
CMS—Chief Operating Officer
FDA—Director, Office of Acquisitions and Grants Services
HRSA—Associate Administrator, Office of Administration and Financial Management
Indian Health Service—Director, Office of Management Services
NIH—Senior Scientific Advisor for Extramural Research, Office of Extramural Research (R&D) and Senior Advisor to the Director (Other than R&D)
PSC—Director, Strategic Acquisition Service
SAMHSA—Executive Officer

■ 64. Revise section 316.603–3 to read as follows:

316.603–3 Limitations.

An official one level above the Contracting Officer shall make the written determination.

316.770–1 [Removed]

■ 65. Remove section 316.770–1.

PART 319—SMALL BUSINESS PROGRAMS

■ 66. Amend section 319.201 by revising paragraph (e) to read as follows:

319.201 General policy.

* * * * *

(e)(1) The Department's Small Business Program shall be carried out by appointed small business specialists (SBS) co-located within the OPDIVs. Appointments, and termination of appointments, shall be made in writing by the Director, Office of Small and Disadvantaged Business Utilization (OSDBU). The Director, OSDBU, will exercise full management authority over small business specialists.

(2) One or more qualified SBS shall be appointed in the following activities:

Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Substance Abuse and Mental Health Services Administration (SAMHSA), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Centers for Disease Control (CDC), Program Support Center (PSC), and the Office of the Secretary (OS).

■ 67. Revise section 319.501 to read as follows:

319.501 General.

(e) Subsequent to the Contracting Officer's recommendation on Form HHS–653, Small Business Set-Aside Review Form, the SBS shall review each proposed acquisition strategy and either concur or non-concur with the Contracting Officer's recommendation. The Small Business Administration's Procurement Center Representative (SBA/PCR) shall also review the acquisition strategy and either concur or non-concur with the Contracting Officer's recommendation. If the Contracting Officer disapproves the SBS's and/or the SBA PCR's set-aside recommendation, the reasons must be documented on the Form HHS–653, and the form placed in the contract file. The Contracting Officer will make the final determination as to whether the proposed acquisition will be set-aside or not.

■ 68. Revise the heading of part 323 to read as follows:

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

■ 69. Amend section 324.103 by revising paragraphs (a), (b), and (c) to read as follows:

324.103 Procedures.

(a) All requests for contract shall be reviewed by the contracting officer to determine whether the Privacy Act requirements are applicable. The Privacy Act requirements are applicable when the contract will require 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 solicitation notification and contract clause required by FAR 24.104 in the solicitation, and the contract clause in the resultant contract. In addition, the contracting officer shall ensure that the solicitation notification, contract clause, and other pertinent information specified in this subpart are included in any contract modification which results in the Privacy Act requirements becoming applicable to a contract.

(b)(1) The Contracting Officer shall identify in the contract work statement the system(s) of records to which the Privacy Act and the implementing regulations are applicable.

(2) The Contracting Officer shall include the clause specified in 352.270–11 in Section H of any RFP or resulting contract to notify the contractor that it and its employees are subject to criminal penalties for violations of the Act (5 U.S.C. 552a(i)) to the same extent as HHS employees. The clause also requires that the contractor ensure that each of its employees knows the prescribed rules of conduct and each contractor employee is aware that he/she is subject to criminal penalties for violations of the Act. These provisions also apply to all subcontracts awarded under the contract which require the design, development or operation of a system of records. 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 specify in the contract work statement and award the disposition to be made of the system(s) of records upon completion of contract performance. The contract work statement 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.

* * * * *

324.202 [Redesignated as 324.203]

■ 70–A. Redesignate section 324.202 as section 324.203.

■ 70–B. Amend section 324.203 by revising paragraph (b) to read as follows:

324.203 Policy.

* * * * *

(b) The Contracting Officer, upon receiving a Freedom of Information Act (FOIA) request, shall follow Department and OPDIV procedures. As necessary, actions should be coordinated with the cognizant Freedom of Information (FOI) Officer and the General Law Division of the Office of General Counsel. The Contracting Officer must remember that only the FOI Officer has the authority to release or deny release of records. While the Contracting Officer should be familiar with the entire FOIA regulation in 45 CFR part 5, particular attention should be focused on §§ 5.65 and 5.66; also of interest are §§ 5.32, 5.33, and 5.35.

PART 325—[REMOVED]

■ 71. Remove part 325.

PART 330—COST ACCOUNTING STANDARDS

■ 72. Revise section 330.201–5 to read as follows:

330.201–5 Waiver.

(c) The requirements of FAR 30.201–5 shall be exercised by the Director, Division of Acquisition Policy (DAP). Requests shall be forwarded through normal acquisition channels to the DAP.

PART 332—CONTRACT FINANCING

■ 73. Revise section 332.402 to read as follows:

332.402 General.

(e) The HCA shall determine whether an advance payment is in the public interest in accordance with FAR 32.402(c)(1)(iii)(A). This authority is non delegable.

■ 74. Amend section 332.407 by revising the introductory text of paragraph (d) to read as follows:

332.407 Interest.

(d) The HCA (not delegable) is authorized to make the determinations in FAR 32.407(d) and as follows. Interest-free advance payments may also be approved for educational institutions and other nonprofit organizations, whether public or private, performing work under nonprofit contracts (without fee) involving health services, educational programs, or social service programs, such as:

* * * * *

■ 75. Revise section 332.501–2 to read as follows:

332.501–2 Unusual progress payments.

(a)(3) The approval of an unusual progress payment shall be made by the HCA (not delegable).

■ 76. Revise section 332.702 to read as follows:

332.702 Policy.

An incrementally funded contract is a multiple year contract in which funds are allocated to cover specific phases or increments of performance.

(a) Incremental funding may be used in cost-reimbursement type contracts for the acquisition of severable services. It shall not be used in contracts for construction or architect-engineer services. Incremental funding allows severable cost-reimbursement type contracts awarded for more than one year to be funded from succeeding fiscal years.

(b) It is Departmental policy that multiple year contracts be fully funded whenever possible. However, incrementally funded contracts may be used when:

(1) A project, which is part of an approved program, is anticipated to be of multiple year duration, but funds are not currently available to cover the entire project;

(2) The project represents a valid need for the fiscal year in which the contract is awarded and for the succeeding fiscal years of the project's duration;

(3) The project is so significant to the approved program that there is reasonable assurance that it will command a high priority for proposed appropriations to cover the entire multiple year duration; and

(4) The statement of work is specific and is defined by separate phases or increments so that, at the completion of each, progress can be effectively measured.

■ 77. Revise section 332.703–1 to read as follows:

332.703–1 General.

(b) The following general guidelines are applicable to incrementally funded contracts:

(1) The estimated total cost of the project (all planned phases or increments) is to be taken into consideration when determining the requirements which must be met before entering into the contract; i.e., justification for noncompetitive acquisition, approval of award, etc.

(2) The RFP and resultant contract are to include a statement of work which describes the total project covering the proposed multiple year period of performance and indicating timetables consistent with planned phases or increments and corresponding allotments of funds.

(3) Offerors' technical and cost proposals must include the entire project and shall show distinct phases or increments and the multiple year period of performance.

(4) Negotiations will be conducted based upon the total project, including all planned phases or increments, and the multiple year period of performance.

(5) Sufficient funds must be obligated under the basic contract to cover no less than the first year of performance, unless the Contracting Officer determines it is advantageous to the Government to fund the contract for a lesser period. In that event, the Contracting Officer shall ensure that the obligated funds are sufficient to cover a complete phase or increment of performance representing a material and measurable part of the total project and the period of time that the funds cover shall be stated in the contract.

(6) An incrementally funded contract must contain precise requirements for progress reports to be sent to the Project and Contracting Officers. These reports will enable the contract to be effectively monitored. The Project Officer shall prepare periodic performance evaluation reports and provide them to the Contracting Officer.

■ 78. Revise section 332.704 to read as follows:

332.704 Limitation of cost or funds.

See subpart 342.71, ''Administrative Actions for Cost Overruns,'' for procedures for handling anticipated cost overruns.

332.705 [Removed]

■ 79. Remove section 332.705.

332.902 [Removed]

■ 80. Remove section 332.902.

PART 333—PROTESTS, DISPUTES, AND APPEALS

333.102 [Amended]

■ 81. Amend section 333.102 by removing paragraph (a).

■ 82. Amend section 333.103 by revising paragraph (f)(3) to read as follows:

333.103 Protests to the agency.

(f) * * *

(3) Protests received after award shall be treated as indicated in FAR 33.103(f)(3).

■ 83. Revise section 333.104 to read as follows:

333.104 Protests to GAO.

(a) *General procedures.* (3)(ii) The DPCO shall process protests filed with GAO, whether pre- or post award. Protest files shall be prepared by the contracting office and distributed as follows: Two copies to the DPCO, one copy to the contracting activity's protest control officer, and one copy to OGC–GLD. In addition to the items listed in 33.104(a)(3)(ii)(A) through (G), the protest file shall include the following documents:

(H) The current status of award. When award has been made, this shall include whether performance has commenced, shipment or delivery has been made, or a stop work order has been issued.

(I) A copy of any mutual agreement to suspend work on a no-cost basis, when appropriate (see FAR 33.104(c)(4)).

(J) Copies of the notice of protest given offerors and other parties when the notice is appropriate (see FAR 33.104(a)(2)).

(K) A copy of the negotiation memorandum, when applicable.

(L) The name and telephone number of the person in the contracting office who may be contacted for information relevant to the protest.

(M) A copy of the competitive range memorandum.

(N) The contracting officer's statement of facts and circumstances, including a discussion of the merits of the protest, and conclusions and recommendations, including documentary evidence on which they are based. The files shall be assembled in an orderly manner and shall have an index of enclosures and any document referred to therein.

(4) The DPCO is responsible for making the necessary distributions referenced in FAR 33.104(a)(4).

(5) The Contracting Officer shall furnish the protest file containing the documentation specified in paragraph (a)(3)(ii) of this section (with the exception of the contracting officer statement of facts and circumstances) and FAR 33.104(a)(3)(ii)(A) through (G) to the DPCO within fourteen (14) calendar days from receipt of the protest. The contracting officer shall submit the contracting officer's statement of facts and circumstances within twenty-one (21) calendar days from receipt of the protest. Since the statute allows only a short time period in which to respond to protests lodged with GAO, the Contracting Officer shall handle each protest on a priority basis. The DPCO shall submit copies of the protest file to GAO, the protestor, and any intervenors in accordance with FAR 33.104(a)(4)(i).

(6) Since the DPCO will furnish the protest file to GAO, the protestor, and any intervenors, comments on the file from the protestor and any intervenors will be sent to the DPCO.

(7) The DPCO, Division of Acquisition Policy (DAP), shall serve as the GAO point of contact for protests lodged with GAO.

(b) *Protests before award.* (1) To make an award notwithstanding a protest, the Contracting Officer shall prepare a finding using the criteria in FAR 33.104(b)(1), have it executed by the HCA (not delegable), and forward it, along with a written request for approval to make the award, to the

Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP).

(2) If the request to make an award notwithstanding the protest is approved by the Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP), the DPCO shall notify GAO. Whether the request is approved or not, the DPCO shall telephonically notify the contracting activity's protest control officer of the decision of the Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP), and the contracting activity's protest control officer shall immediately notify the Contracting Officer. The DPCO shall confirm the decision by memorandum to the contracting activity's protest control officer.

(c) *Protests after award.* (2) If the Contracting Officer believes performance should be allowed to continue notwithstanding the protest, a finding shall be prepared by the Contracting Officer using the criteria in FAR 33.104(c)(2), executed by the HCA (not delegable), and forwarded, along with a written request for approval, to the Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP). The same procedures for notification stated in paragraph (b)(2) of this section shall be followed.

(d) *Findings and notice.* The written notice required by FAR 33.104(d) shall be provided to the protestor and any intervenors by the DPCO.

(g) *Notice to GAO.* The Deputy Assistant Secretary for Acquisition Management and Policy (DASAMP) shall be the official to comply with the requirements of FAR 33.104(g).

■ 84. Revise section 333.203 to read as follows:

333.203 Applicability.

(c) The Secretary has designated the Armed Services Board of Contract Appeals (ASBCA) as the authorized ''Board'' to hear and determine disputes for the Department.

■ 85. Revise section 333.211 to read as follows:

333.211 Contracting officer's decision.

(a)(2) The contracting officer shall refer a proposed final decision to the Office of General Counsel-General Law Division (OGC–GLD), for advice as to the legal sufficiency and format before sending the final decision to the contractor. The contracting officer shall provide OGC–GLD with the pertinent documents with the submission of each proposed final decision.

(a)(4)(v) When using the paragraph in FAR 33.211 (a)(4)(v), the contracting officer shall insert the words ''Armed Services'' before each mention of the term ''Board of Contract Appeals''.

(h) At any time within the period of appeal, the contracting officer may modify or withdraw his/her final decision. If an appeal from the final decision has been taken to the ASBCA, the contracting officer will forward his/her recommended action to OGC–GLD with the supplement to the contract file which supports the recommended correction or amendment.

■ 86. Revise section 333.212 to read as follows:

333.212 Contracting officer's duties upon appeal.

(a) Appeals shall be governed by the rules set forth in the ''Rules of the Armed Services Board of Contract Appeals,'' or by the rules established by the U.S. Court of Federal Claims, as appropriate.

(b) The Office of General Counsel-General Law Division (OGC-GLD) is designated as the Government Trial Attorney to represent the Government in the defense of appeals before the ASBCA. A decision by the ASBCA will be transmitted by the Government Trial Attorney to the appropriate contracting officer for compliance in accordance with the ASBCA's decision.

(c) If an appeal is filed with the ASBCA, the contracting officer shall assemble a file within 30 days of receipt of an appeal, or advice that an appeal has been filed, that consists of all documents pertinent to the appeal, including:

(1) The decision and findings of fact from which the appeal is taken;

(2) The contract, including specifications and pertinent modifications, plans and drawings;

(3) All correspondence between the parties pertinent to the appeal, including the letter or letters of claim in response to which the decision was issued;

(4) Transcripts of any testimony taken during the course of proceedings, and affidavits or statements of any witness on the matter in dispute made prior to the filing of the notice of appeal with the Board; and

(5) Any additional information considered pertinent. The contracting officer shall furnish the appeal file to the Government Trial Attorney for review and approval. After approval, the contracting officer shall prepare four copies of the file, one for the ASBCA, one for the appellant, one for the Government Trial Attorney, and one for the contracting office.

(d) At all times after the filing of an appeal, the contracting officer shall render whatever assistance is requested by the Government Trial Attorney. When an appeal is set for hearing, the concerned contracting officer shall be responsible for providing Government witnesses and specified physical and documentary evidence to the Trial Attorney. The Trial Attorney shall ensure the presence of all witnesses and documentary evidence at both the pre-hearing conference and hearing.

(e) If a contractor which has filed an appeal with the ASBCA elects to accept fully the decision from which the appeal was taken, or any modification to it, and gives written notification of acceptance to the Government Trial Attorney or the concerned contracting officer, the Government Trial Attorney will notify the ASBCA of the disposition of the dispute in accordance with Rule 27 of the ASBCA.

(f) If the contractor has elected to appeal to the U.S. Court of Federal Claims, the U.S. Department of Justice will represent the Department. However, the contracting officer shall still coordinate all actions through OGC–GLD.

■ 87. Amend section 333.212–70 by revising paragraph (a) to read as follows:

333.212–70 Formats.

(a) The following format is suggested for use in transmitting appeal files to the ASBCA:

Your reference:
(Docket No.)
(Name)
Recorder, Armed Services Board of Contract Appeals
Skyline Six 5109 Leesburg Pike
Falls Church, Virginia 22041

Dear (Name):

Transmitted herewith are documents relative to the appeal under Contract No. ____ with the _____
(Name of contractor)
in accordance with the procedures under Rule 4. The Government Trial Attorney for this case is
(*Insert General Law Division, Office of General Counsel, Department of Health and Human Services, 330 Independence Avenue, SW., Washington, DC 20201*).

The request for payment of charges resulting from the processing of this appeal should be addressed to:
(Insert name and address of cognizant finance office.)

Sincerely yours,

Contracting Officer
Enclosures

* * * * *

PART 334—[REMOVED]

■ 88. Remove part 334.

PART 335—RESEARCH AND DEVELOPMENT CONTRACTING

■ 89. Amend section 335.070–2 by revising the introductory text and paragraph (a) to read as follows:

335.070–2 Amount of cost-sharing.

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

(a) The amount of cost participation should depend on the extent to which the research effort or results are likely to enhance the performing organization's capability, expertise, or competitive position, and the value of this enhancement to the performing organization. It should be recognized that those organizations which are predominantly engaged in research and development have little or no production or other service activities and may not be in a favorable position to derive a monetary benefit from their research under Federal agreements. Therefore, contractor cost participation could reasonably range from as little as 1 percent or less of the total project cost, to more than 50 percent of the total project cost. Ultimately, the Contracting Officer should bear in mind that cost-sharing is a negotiable item. As such, the amount of cost-sharing should be proportional to the anticipated value of the contractor's gain.

* * * * *

■ 90. Add part 339 to read as follows:

PART 339—ACQUISITION OF INFORMATION TECHNOLOGY

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

339.201–10 Clarification.

FAR Subpart 39.2, Electronic and Information Technology, requires Federal agencies to ensure that, when acquiring EIT, Federal employees with disabilities and members of the public with disabilities have access to and use of information and data that is comparable to individuals without disabilities. This EIT access requirement does not apply to a contractor's internal workplaces. EIT that is not used nor accessed by Federal employees or members of the public is not subject to the Architectural and Transportation Barriers Compliance Board (Access Board) standards. Contractors in their professional capacity are not members of the public for purposes of Section 508.

339.201–70 Required provision and contract clause.

When acquiring EIT, the Contracting Officer shall insert the provision at 352.270–19(a) in solicitations and the clause in 352.270–19(b) in contracts and orders for projects that will develop, purchase, maintain, or use electronic and information technology (EIT), unless these EIT products and/or services are incidental to the project. (Note: Other exceptions to this requirement can be found at FAR 39.204.)

PART 342—CONTRACT ADMINISTRATION

■ 91. Revise section 342.705 to read as follows:

342.705 Final indirect cost rates.

(a) The Director, Division of Cost Allocation of the Program Support Center, within each servicing HHS regional office, has been delegated the authority to establish indirect cost rates, research patient care rates, and, as necessary, fringe benefit, computer, and other special costing rates for use in contracts and grants awarded to State and local governments, colleges and universities, hospitals, and other nonprofit organizations.

(b) The Division of Financial Advisory Services of the National Institutes of Health has the authority to establish indirect cost rates, fringe benefit rates, etc., for use in contracts and grants awarded to commercial organizations.

■ 92. Revise section 342.7001 to read as follows:

342.7001 Purpose.

Contract monitoring is an essential element of contract administration and is performed jointly by the Project Officer and the Contracting Officer. This subpart describes the Department's operating concepts.

■ 93. Revise section 342.7002 to read as follows:

342.7002 Contract monitoring responsibilities.

(a) The contract establishes the obligations of both the Government and the contractor. The Contracting Officer is the only person authorized to make changes to the contract. The Contracting Officer must confirm all changes in writing.

(b) The Contracting Officer is responsible for assuring compliance with all the terms and conditions of the contract. The Contracting Officer shall inform the contractor by letter (if not already stipulated in the contract) of the authorities and responsibilities of the Government personnel involved with the contract.

(c) The Contracting Officer must depend on program, technical, and other personnel for assistance and advice in monitoring the contractor's performance, and in other areas of postaward administration. The Contracting Officer must assure that these individuals understand and carry out their assigned responsibilities. The individual roles and corresponding responsibilities typically involve, but are not limited to, the following:

(1) The role of program and technical personnel in monitoring the contract is to assist and/or advise the Contracting Officer or act as his/her representative when so designated by the Contracting Officer. Activities may include:

(i) Providing technical monitoring during contract performance, and issuing letters to the contractor and Contracting Officer relating to delivery, acceptance, or rejection in accordance with the terms of the contract;

(ii) Assessing contractor performance, including inspection and testing of products and evaluation of reports and data;

(iii) Recommending necessary changes to the schedule of work and period of performance in order to accomplish the objectives of the contract. Program officials must provide the Contracting Officer a written request along with an appropriate justification and a funding document if additional funds are needed;

(iv) Reviewing invoices/vouchers and recommending approval/disapproval action by the Contracting Officer, to include comments regarding anything unusual discovered in the review;

(v) Reviewing and recommending approval or disapproval of subcontractors, overtime, travel, and key personnel changes; and

(vi) Participating, as necessary, in various phases of the contract closeout process.

(2) The role of the Project Officer in monitoring the contract includes the applicable activities set forth in paragraph (c)(1) of this section. The Project Officer also shall do the following:

(i) Submit periodic reports to the Contracting Officer that concisely explain the status of the contract, and include recommended actions for any problems reported. Provide the Contracting Officer with written notification of evaluation and approval/disapproval of contract deliverables and of completion of tasks or phases. The Contracting Officer or designee will provide the contractor with written

notification of approval or disapproval and include a copy in the contract file;

(ii) Monitor the technical aspects of the contract, identify existing and potential problems that threaten performance, and immediately inform the Contracting Officer of deviations from contract objectives or from any technical or delivery requirements;

(iii) Immediately notify the head of the program office whenever it is determined that objectives are not being met and provide specific recommendations of actions to be taken. The Contracting Officer shall receive a copy of the Project Officer's report and recommendations;

(iv) Within 120 days after contract completion, submit a final written assessment report to the Contracting Officer. The report should include analysis of the contractor's performance, including the contract and program objectives achieved and missed. A copy of the final assessment report shall be forwarded to the head of the program office responsible for the program for management review and follow-up, as necessary; and

(v) Accompany and/or provide, when requested, technical support to the HHS auditor in the conduct of visual inspections.

(3) The roles of the contract administrator, auditor, cost analyst, and property administrator are to assist and/or advise the Contracting Officer in postaward administration activities such as:

(i) Evaluation of contractor systems and procedures, to include accounting policies and procedures, purchasing policies and practices, property accounting and control, wage and salary plans and rate structures, personnel policies and practices, etc.;

(ii) Processing of disputes under the Disputes clause and any resultant appeals;

(iii) Modification or termination of the contract; and

(iv) Determination of the allowability of cost charges to incentive or cost-reimbursement type contracts and progress payments under fixed-price contracts. This is especially important when award is made to new organizations or those with financial weaknesses.

(d) The Contracting Officer is responsible for assuring that contractor performance and contract monitoring conform with contract terms. If performance is not satisfactory or if problems are anticipated, it is essential that the Contracting Officer take immediate action to protect the Government's rights under the contract. The Contracting Officer shall notify his/her immediate supervisor of problems that cannot be resolved within contract limitations and whenever contract or program objectives are not met. The notification shall include a statement of action being taken by the Contracting Officer.

■ 94. Revise section 342.7003–1 to read as follows:

§ 342.7003–1 Policy.

(a) All solicitations and resultant contracts (other than awards made using simplified acquisition procedures) shall contain the withholding of contract payments clause at 352.232–9, and an excusable delays clause, or a clause which incorporates the definition of excusable delays. Use the excusable delays clause at 352.249–14 when the solicitation and resultant contract (other than purchase orders) does not contain a default or other excusable delays clause.

(b) When appropriate, the Contracting Officer may withhold any contract payment when a required report is overdue, or the contractor fails to perform or deliver required work or services.

■ 95. Revise section 342.7003–2 to read as follows:

§ 342.7003–2 Procedures.

(a) The Contracting Officer is responsible for initiating immediate action to protect the Government's rights whenever the contractor fails to comply with either the delivery or reporting terms of the contract. Compliance with the reporting terms includes those reports to be submitted directly to the payment office. The payment office shall notify the Contracting Officer promptly when such a report is not submitted on time.

(b) When the contract contains a termination for default clause, the contractor's failure to submit any report, perform services, or deliver work when required by the contract is considered a default in performance. The Contracting Officer shall immediately issue a formal ten-day cure notice pursuant to FAR 49.607. The notice shall include a statement to the effect that payments will be withheld if the default is not cured within the time frame specified in the notice or if the default is not determined to be excusable.

(1) If the default is cured or is determined to be excusable, the Contracting Officer shall not initiate the withholding action.

(2) If the default is not determined to be excusable or a response is not received within the allotted time, the Contracting Officer shall initiate withholding action on all contract payments and shall determine whether termination for default or other action would be in the best interest of the Government.

(c) When the contract does not contain a termination for default clause, the contractor's failure to submit any required report, perform services, or deliver work when required by the contract shall be considered a failure to perform. The Contracting Officer shall immediately issue a written notice to the contractor specifying the failure and providing a ten-day period (or longer period if the Contracting Officer deems it necessary) in which the contractor shall cure the failure or provide reasons for an excusable delay. The notice shall include a statement to the effect that payments will be withheld if the default is not cured within the time specified in the notice or if the default is not determined to be excusable.

(1) If the failure is cured or is determined to be excusable, the Contracting Officer shall not initiate the withholding action.

(2) If the failure is not determined to be excusable or a response is not received within the allotted time, the Contracting Officer shall initiate withholding action on all contract payments and shall determine whether termination for convenience or other action would be in the best interest of the Government.

(d) The Contracting Officer should consult FAR subpart 49.4 for further guidance before taking any of the actions described in this section.

■ 96. Revise section 342.7003–3 to read as follows:

§ 342.7003–3 Withholding payments.

(a) When making the determination that contract payments should be withheld in accordance with the Withholding of Contract Payments clause, the Contracting Officer shall immediately notify the servicing finance office in writing of the determination to withhold payments. The notice of suspension shall contain all information necessary for the finance office to identify the contract, *i.e.*, contract number, task/delivery order number, contractor name and address, etc.

(b) The Contracting Officer shall immediately notify the contractor in writing that payments have been suspended until the default or failure is cured.

(c) When the contractor cures the default or failure, the Contracting Officer shall immediately notify, in writing, all recipients of the notice of suspension that the suspension is to be lifted and contract payments are to be resumed.

(d) When exercising actions regarding the withholding of payment procedures, the Contracting Officer must be careful not to waive any of the Government's rights when corresponding with the contractor or when taking any other actions.

■ 97. Revise section 342.7100 to read as follows:

§ 342.7100 Scope of subpart.

This subpart sets forth the procedures to follow when a cost overrun is anticipated. A cost overrun occurs when the allowable actual cost of performing a cost-reimbursement type contract exceeds the total estimated cost specified in the contract.

■ 98. Amend section 342.7101–2 by revising the introductory text of paragraph (a) and paragraph (b)(3) to read as follows:

§ 342.7101–2 Procedures.

(a) Upon notification that a cost overrun is anticipated, the Contracting Officer shall inform the contractor to submit a request for additional funds which shall include:

* * * * *

(b) * * *

(3) Maintain continuous follow-up with the program office to obtain a timely decision as to whether the work under the contract should continue and additional funds be provided, or the contract terminated. An appropriate written statement and funding authority, or a formal request for termination, must support the decision of the program office. After receiving the decision by the program office, the Contracting Officer shall promptly notify the contractor in writing of the following:

(i) The specified amount of additional funds allotted to the contract; or

(ii) Work will be discontinued when the allotted funds are exhausted, and any work performed after that date is at the contractor's risk; or

(iii) The Government is considering whether to allot additional funds to the contract and will notify the contractor as soon as possible, but that any work performed after the currently allotted funds are exhausted is at the contractor's risk. Timely, formal notification of the Government's intention is essential in order to preclude loss of contractual rights in the event of dispute, termination, or litigation.

* * * * *

PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 99. Revise section 352.202–1 to read as follows:

§ 352.202–1 Definitions.

As prescribed in 302.201, use the FAR Definitions clause at 52.202–1 as modified:

Definitions (January 2006)

(a) In accordance with 52.202–1(a)(1), substitute the following as paragraph (a):

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

(b) In accordance with 52.202–1(a)(1), add the following paragraph (h):

''(h) The term ''Project Officer'' means the person who monitors the technical aspects of contract performance. The Project Officer is not authorized to issue any instructions or directions which cause any increase or decrease in the scope of work which would result in the increase or decrease in the price of this contract, or changes in the delivery schedule or period of performance of this contract. If applicable, the Project Officer is not authorized to receive or act upon any notification or revised cost estimate provided by the Contractor in accordance with the Limitation of Cost or Limitation of Funds clauses of this contract.''

■ 100. Revise section 352.215–1 to read as follows:

§ 352.215–1 Instructions to offerors—Competitive acquisition.

Insert the following paragraph (e) in place of paragraph (e) of the provision at FAR 52.215–1:

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted: ''Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).''

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

''Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation.''

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

■ 101. Revise section 352.215–70 to read as follows:

§ 352.215–70 Late proposals and revisions.

As prescribed in 315.208, the following provision may be included in the solicitation:

Late Proposals and Revisions (January 2006)

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

(End of provision)

■ 102. Amend section 352.216–72 by revising the title and paragraph (a)(4) of the ''Additional Cost Principles'' clause to read as follows:

§ 352.216–72 Additional cost principles.

* * * * *

Additional Cost Principles (January 2006)

(a) * * *

(4) Bid and proposal costs do not include independent research and development costs

covered by the following paragraph, or preaward costs covered by paragraph 36 of Attachment B to OMB Circular A–122.

* * * * *

■ 103. Revise section 352.223–70 to read as follows:

352.223–70 Safety and health.

The following clause shall be used as prescribed in 323.7002:

Safety and Health (January 2006)

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

(1) In addition, the following regulations must be followed 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 the Occupational Health and Safety Administration (OSHA) and included in 29 CFR Part 1910. These regulations are available at *http://www.osha.gov/comp-links.html.*

(ii) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). Copies may be obtained from the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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

(i) Biosafety in Microbiological and Biomedical Laboratories, CDC and NIH, HHS. This publication is available at *http://bmbl.od.nih.gov/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 can be obtained by telephoning 800–624–8373. It also 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 project or other appropriate officers, 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, an equitable adjustment will be made 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; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report 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 stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

■ 104. Revise section 352.224–70 to read as follows:

352.224–70 Confidentiality of information.

The following clause covers the policy set forth in subpart 324.70 and is used in accordance with the instructions set forth in 324.7004.

Confidentiality of Information (January 2006)

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

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

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

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

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

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

(End of clause)

■ 105. Amend section 352.228–7 by revising paragraph (d) of the ''Insurance—Liability to Third Persons'' clause to read as follows:

352.228–7 Insurance—Liability to third persons.

* * * * *

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

* * * * *

■ 106. Revise section 352.232–9 to read as follows:

352.232–9 Withholding of contract payments.

Insert the following clause in all solicitations and contracts other than awards made using simplified acquisition procedures:

Withholding of Contract Payments (January 2006)

Notwithstanding any other payment provisions of this contract, failure of the Contractor to submit required reports when due or failure to perform or deliver required work, supplies, or services, may result in the withholding of payments under this contract unless such failure arises out of causes beyond the control, and without the fault or negligence of the Contractor as defined by the clause entitled ''Excusable Delays'' or ''Default'', as applicable. The Government shall immediately notify the Contractor of its

intention to withhold payment of any invoice or voucher submitted.

(End of clause)

352.232–74 [Removed]

■ 107. Remove section 352.232–74.

■ 108. Revise section 352.232–75 to read as follows:

352.232–75 Incremental funding.

The following provision shall be included in all requests for proposals whenever the use of incremental funding is contemplated:

Incremental Funding (January 2006)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds, as specified in FAR 52.232–22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modification. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232–22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.

(End of provision)

■ 109. Revise section 352.233–70 to read as follows:

352.233–70 Litigation and claims.

Insert the following clause in all solicitations and resultant cost-reimbursement contracts:

Litigation and Claims (January 2006)

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

■ 110. Revise section 352.249–14 to read as follows:

352.249–14 Excusable delays.

Insert the following clause in all solicitations and resultant contracts, other than awards made using simplified acquisition procedures:

Excusable Delays (January 2006)

(a) Except with respect to failures of subcontractors, the Contractor shall not be considered to have failed in performance of this contract if such failure arises out of causes beyond the control and without the fault or negligence of the Contractor.

(b) Such causes may include, but are not restricted to, acts of God or of the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, and unusually severe weather, but in every case the failure to perform must be beyond the control and without the fault or negligence of the Contractor. If the failure to perform is caused by the failure of a subcontractor to perform, and if such failure arises out of causes beyond the control of both the Contractor and subcontractor, and without the fault or negligence of either of them, the Contractor shall not be deemed to have failed in performance of the contract, unless: (1) The supplies or services to be furnished by the subcontractor were obtainable from other sources, (2) the Contracting Officer ordered the Contractor in writing to procure such supplies or services from such other sources, and (3) the Contractor failed to comply with such order. Upon request of the Contractor, the Contracting Officer shall ascertain the facts and extent of such failure and if the Contracting Officer determines that any failure to perform was caused by circumstances beyond the control and without the fault or negligence of the Contractor, the delivery schedule shall be revised accordingly, subject to the rights of the Government under the termination clause contained in this contract. (As used in this clause, the terms ''subcontractor'' and ''subcontractors'' mean subcontractor(s) at any tier.)

(End of clause)

■ 111. Amend section 352.270–1 by revising the introductory text of the section and paragraph (c)(3) of the Accessibility clause to read as follows:

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

Use the following clause in accordance with 370.102:

Accessibility of Meetings, Conferences, and Seminars to Persons With Disabilities (Jan 2001)

* * * * *

(c) * * *

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

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

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

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

(End of clause)

* * * * *

■ 112. Amend section 352.270–2 by revising the introductory text to read as follows:

352.270–2 Indian preference.

Use the following clause as prescribed in 370.202(a):

* * * * *

■ 113. Revise section 352.270–3 to read as follows:

352.270–3 Indian preference program.

Use the following clause as prescribed in 370.202(b):

Indian Preference Program (January 2006)

(a) In addition to the requirements of the clause of this contract entitled ''Indian Preference,'' the Contractor agrees to establish and conduct an Indian preference program which will expand opportunities for Indians to receive preference for employment

and training in connection with the work to be performed under this contract, and which will expand the opportunities for Indian organizations and Indian-owned economic enterprises to receive a preference in the awarding of subcontracts. In this connection, the Contractor shall:

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

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

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

(4) Establish and conduct a subcontracting program which gives preference to Indian organizations and Indian-owned economic enterprises as subcontractors and suppliers under this contract. The Contractor shall give public notice of existing subcontracting opportunities and, to the extent feasible and consistent with the efficient performance of this contract, shall solicit bids or proposals only from Indian organizations or Indian-owned economic enterprises. The Contractor shall request assistance and information on Indian firms qualified as suppliers or subcontractors from the Tribe(s) on or near whose reservation(s) the work under the contract is to be performed. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to be contacted in regard to the request for assistance and information. Public notices and solicitations for existing subcontracting opportunities shall provide an equitable opportunity for Indian firms to submit bids or proposals by including: (i) A clear description of the supplies or services required, including quantities, specifications, and delivery schedules which facilitate the participation of Indian firms; (ii) A statement indicating that preference will be given to Indian organizations and Indian-owned economic enterprises in accordance with section 7(b) of Public Law 93–638 (88 Stat. 2205; 25 U.S.C. 450e(b)); (iii) Definitions for the terms ''Indian organization'' and ''Indian-owned economic enterprise'' as prescribed under the ''Indian Preference'' clause of this contract; (iv) A statement to be completed by the bidder or offeror that it is an Indian organization or Indian-owned economic enterprise; and (v) A closing date for receipt of bids or proposals which provides sufficient time for preparation and submission of a bid or proposal. If after soliciting bids or proposals from Indian organizations and Indian-owned economic enterprises, no responsive bid or acceptable proposal is received, the Contractor shall comply with the requirements of paragraph (d) of the ''Indian Preference'' clause of this contract. If one or more responsible bids or acceptable proposals are received, award shall be made to the low responsible bidder or acceptable offeror if the price is determined to be reasonable. If the low responsive bid or acceptable proposal is determined to be unreasonable as to price, the Contractor shall attempt to negotiate a reasonable price and award a subcontract. If a reasonable price cannot be agreed upon, the Contractor shall comply with the requirements of paragraph (d) of the ''Indian Preference'' clause of this contract.

(5) Maintain written records under this contract which indicate: (i) The numbers of Indians seeking employment for each employment position available under this contract; (ii) The number and types of positions filled by Indians and non-Indians; (iii) The total number of Indians employed under this contract; (iv) For those positions where there are both Indian and non-Indian applicants, and a non-Indian is selected for employment, the reason(s) why the Indian applicant was not selected; (v) Actions taken to give preference to Indian organizations and Indian-owned economic enterprises for subcontracting opportunities which exist under this contract; (vi) Reasons why preference was not given to Indian firms as subcontractors or suppliers for each requirement where it was determined by the Contractor that such preference would not be consistent with the efficient performance of the contract; and (vii) The number of Indian organizations and Indian-owned economic enterprises contacted, and the number receiving subcontract awards under this contract.

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

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

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

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

(2) ''Indian reservation'' includes Indian reservations, public domain Indian Allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 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 be expected to commute to and from in the course of a work day.

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

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

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

(End of clause)

■ 114. Amend section 352.270–4 by revising the introductory text to read as follows and by replacing the word ''permforming'' in the table with ''performing:''

352.270–4 Pricing of adjustments.

Insert the following clause in all solicitations and resultant fixed-priced contracts other than awards made using simplified acquisition procedures.

* * * * *

■ 115. Revise section 352.270–5 to read as follows:

352.270–5 Key personnel.

Insert the following clause in all solicitations and resultant contracts which require Key Personnel, regardless of the type of contract.

Key Personnel (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The

Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

(End of clause)

■ 116. Revise section 352.270–6 to read as follows:

352.270–6 Publications and publicity.

Insert the following clause in all solicitations and resultant contracts.

Publications and Publicity (January 2006)

(a) Unless otherwise specified in this contract and the Confidentiality of Information clause is included, the Contractor is encouraged to publish the results of its work under this contract. A copy of each article submitted by the Contractor for publication shall be promptly sent to the Project Officer. The Contractor shall also inform the Project Officer when the article or other publication is published, and furnish a copy of it as finally published.

(b) The Contractor shall include in any publication resulting from work performed under this contract a disclaimer reading as follows:

''The views expressed in written conference materials or publications and by speakers and moderators at HHS-sponsored conferences, do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.''

(c) Unless authorized by the Project Officer, the contractor shall not display the HHS logo on any conference materials or publications.

(End of clause)

■ 117. Revise section 352.270–7 to read as follows:

352.270–7 Paperwork Reduction Act.

Insert the following clause in all solicitations and contracts subject to the Paperwork Reduction Act requirements regarding the collection and recording of information from 10 or more persons other than Federal employees.

Paperwork Reduction Act (January 2006)

(a) This contract involves a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties; therefore, the Paperwork Reduction Act of 1995 (Pub. L. 104–13) 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 first obtaining clearance from the Office of Management and Budget (OMB). Contractors and Project Officers should be guided by the provisions of 5 CFR part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

(b) The Contractor shall not expend any funds or begin any data collection until OMB Clearance is received. Once OMB Clearance is received from the Project Officer, the Contracting Officer shall provide the Contractor with written notification authorizing the expenditure of funds and the collection of data. The Contractor must allow at least 120 days for OMB clearance. Excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Contractor will be considered in accordance with the Excusable Delays or Default clause of this contract.

(End of clause)

■ 118. Revise section 352.270–8 to read as follows:

352.270–8 Protection of human subjects.

(a) Include the following provision in solicitations expected to involve human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (January 2006)

(a) Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by HHS.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR part 46.

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

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OPDIV will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OHRP, (telephone: 301–496–7014), is recommended.

(e) In accordance with 45 CFR part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site: *http://www.hhs.gov/ohrp/*.

(f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

(b) Include the following clause in solicitations and resultant contracts involving human subjects:

Protection of Human Subjects (January 2006)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Office of Public Health and Science (OPHS). 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 be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during the performance of this contract, the Contracting Officer determines, in consultation with the OHRP, OPHS, ASH, that 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. 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 OHRP, OPHS, ASH, terminate this contract in a whole or in part, and the Contractor's name may be removed form the list of those contractors with approved Health and Human Services Human Subject Assurances.

(End of clause)

■ 119. Revise section 352.270–9 to read as follows:

352.270–9 Care of laboratory animals.

(a) Include the following provision in solicitations expected to involve vertebrate animals:

Notice to Offerors of Requirement for Compliance With the Public Health Service Policy on Humane Care and Use of Laboratory Animals (January 2006)

The PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No award involving the use of animals shall be made unless OLAW approves the Animal Welfare Assurance. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, contact OLAW at NIH, Bethesda, Maryland 20892 (301–496–7163).

(End of provision)

(b) Include the following clause in all solicitations and resultant contracts involving research on vertebrate animals:

Care of Live Vertebrate Animals (January 2006)

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

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

(c) The Contractor agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources 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 be used.

(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/or 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 approved PHS 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.

(End of clause)

■ 120. Add sections 352.270–10 through 352.270–19 to subpart 352.2 to read as follows:

Subpart 352.2—Texts of Provisions and Clauses

* * * * *

352.270–10 Anti-lobbying.
352.270–11 Privacy Act.
352.270–12 Pro-Children Act.
352.270–13 Tobacco-free facilities.
352.270–14 Restriction on use of human subjects.
352.270–15 Salary rate limitation.
352.270–16 Native American Graves Protection and Repatriation Act.
352.270–17 Crime Control Act—Reporting of child abuse.
352.270–18 Crime Control Act—Requirement for background checks.
352.270–19 Electronic information and technology accessibility.

Subpart 352.2—Texts of Provisions and Clauses

* * * * *

352.270–10 Anti-lobbying.

Insert the following clause in all solicitations and resultant contracts expected to exceed $100,000:

Anti-Lobbying (January 2006)

Pursuant to the current HHS annual appropriations act, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for (i) publicity or propaganda purposes; (ii) the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself; or (iii) payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

(End of Clause)

352.270–11 Privacy Act.

The following clause shall be used as prescribed in 324.103(a):

Privacy Act (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term ''system of records'' means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded 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 to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

352.270–12 Pro-Children Act.

Insert the following clause in all solicitations and resultant contracts and orders, regardless of dollar amount, for (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 on a routine or regular basis pursuant to the Pro-Children Act of 1994:

Pro-Children Act of 1994 (January 2006)

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.

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

Failure to comply with the Act may result in the imposition of a civil monetary penalty in an amount not to exceed $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity. Each day a violation continues constitutes a separate violation.

(End of clause)

352.270–13 Tobacco-free facilities.

Insert the following clause in all new solicitations and resultant contracts and orders (including construction) and all modifications resulting from the exercise of an option under a contract or order, regardless of dollar value, where some or all of the Contractor's performance, will take place on HHS properties. This clause is not required to be included if contract or order performance requires only that Contractor staff attend occasional meetings on HHS properties. In this case, Contractor employees are considered ''visitors.'' Further, for any proposed or existing construction contract or order, the Contracting Officer should coordinate any exceptions to the policy raised by an incumbent or potential Contractor based on union or collective bargaining agreements with the designated OPDIV tobacco-free policy contact point for final disposition.

Tobacco-Free Facilities (January 2006)

In accordance with Department of Health and Human Services (HHS) policy, the Contractor and its staff are prohibited from using tobacco products of any kind (e.g., cigarettes, cigars, pipes, and smokeless tobacco) while on any HHS property, including use in personal or company vehicles operated by Contractor employees while on an HHS property. This policy also applies to all subcontracts awarded under the contract or order.

The term ''HHS properties'' includes all properties owned, controlled and/or leased by HHS when totally occupied by HHS, including all indoor and outdoor areas of such properties. Where HHS only partially occupies such properties, it includes all HHS-occupied interior space. Where HHS leases space in a multi-occupant building or complex, the tobacco-free HHS policy will apply to the maximum area permitted by law and compliance with the provisions of any current lease agreements.

The Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understand, and comply with this policy.

(End of clause)

352.270–14 Restriction on use of human subjects.

If the Contractor has an approved Federal-wide assurance of compliance in place, but the certification that the Institutional Review Board (IRB) designated under the assurance has reviewed and approved the research cannot be completed prior to contract award 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), the award may be made without the requisite certification as long as the contract is appropriately conditioned. Under these conditions, insert the following clause in applicable contracts:

Restriction on Use of Human Subjects (January 2006)

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

(End of clause)

352.270–15 Salary rate limitation.

Insert the following clause in all new NIH, SAMHSA, and AHRQ solicitations and resultant contracts and orders (except fixed-price completion contracts) and modifications of existing contracts for projects that support extramural activities. Projects that support extramural activities include extramural R&D, SAMHSA's mission-related requirements, and those activities commonly referred to as ''extramural R&D support.''

OR

Insert the following clause in all new NIH, SAMHSA, and AHRQ solicitations and resultant contracts (except fixed-price completion contracts) and modifications of existing contracts for extramural R&D and SAMHSA's mission-related requirements. Projects that are not considered R&D but that support extramural R&D activities (commonly referred to as ''extramural R&D support'') are OR are not included.

Salary Rate Limitation (January 2006)

Pursuant to the applicable HHS appropriations acts cited in the table below, the Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the salary level in effect on the date the expense is incurred as shown in the table below.

For purposes of the salary 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 appointment whether that individual's time is spent on research, teaching, patient care, or other activities. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

The salary rate limitation also applies to individuals performing under subcontracts. However, it does not apply to fees paid to consultants. If this is a multiple-year contract, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish contract funding.

Public law	Period covered	Salary limitation (based on Executive Level I)
108–447, Div F, Title II, General Provisions, Section 204	10/01/05—12/31/05	$180,100
109–149, General Provisions, Section 204	01/01/06—until revised	$183,500

Executive Level salaries for the current and prior periods can be found at the following Web site: *http://www.opm.gov/oca/05tables/html/ex.asp.* Click on ''Salaries and Wages'' and then scroll to the bottom of the page to select the desired period.

(End of Clause)

352.270–16 Native American Graves Protection and Repatriation Act.

Insert the following clause in any solicitation and resultant contract or order that requires performance on tribal lands and all solicitations and resultant contracts or orders for construction on Federal or tribal lands, regardless of dollar amount:

Native American Graves Protection and Repatriation Act (January 2006)

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

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.

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 date that the appropriate authorities certify receipt of the discovery notice and the date on which the Contractor may resume activities shall be provided to the Contractor by the Contracting Officer.

(End of clause)

352.270–17 Crime Control Act—Reporting of child abuse.

Insert the following clause in all solicitations and resultant contracts and orders, regardless of dollar amount, where performance will take place on Federal land or in a federally-operated (or contracted) facility and that involve the professions/activities performed by persons specified in the Crime Control Act of 1990, including, but not limited to, 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:

Crime Control Act of 1990—Reporting of Child Abuse (January 2006)

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.

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

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 should 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®) should be called. Any covered professional failing to make a timely report of such incident shall be guilty of a Class B misdemeanor.

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

(End of clause)

352.270–18 Crime Control Act—Requirement for background checks.

Insert the following clause in all solicitations and resultant contracts and orders, regardless of dollar amount, for all 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 (Act):

Crime Control Act of 1990—Requirement for Background Checks (January 2006)

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.

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.

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

(End of clause)

352.270–19 Electronic information and technology accessibility.

(a) The following clause shall be used in solicitations as provided in 339.201–70:

Electronic and Information Technology Accessibility (January 2006)

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by Public Law 105–220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that all EIT acquired must ensure that:

(1) 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; and

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

This requirement includes the development, procurement, maintenance, and/or use of EIT products/services; therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards. Information about Section 508 is available at *http://www.section508.gov/.*

(End of provision)

(b) The following clause shall be used in contracts and orders as provided in 339.201–70:

Electronic and Information Technology Accessibility (January 2006)

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by Public Law 105–220 under Title IV (Rehabilitation Act Amendments of 1998), all Electronic and Information Technology (EIT) developed, procured, maintained, and/or used under this contract shall be in compliance with the ''Electronic and Information Technology Accessibility Standards'' set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the ''Access Board'') in 36 CFR part 1194. The complete text of Section 508 Final Standards can be accessed at *http://www.access-board.gov/sec508/standards.htm.*

The standards applicable to this requirement are [identified in the Statement of Work/listed below]:

(Select the appropriate phrase within the brackets [ ] and complete if necessary and identify location of/provide complete list of applicable provisions. Use the Buy accessible wizard at *http://www.buyaccessible.gov* if necessary or contact your Section 508 Coordinator)

Vendors may document conformance using [attached documentation/industry-standard Voluntary Product Accessibility Template at *http://www.itic.org/archives/articles/20040506/faq_voluntary_product_accessibility_template_vpat.php*] (select the appropriate phrase within the brackets [ ]). Vendors should provide detailed information necessary for determining compliance, including defined contractor-incidental exceptions.

(End of clause)

PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

■ 121. Revise section 370.102 to read as follows:

370.102 Responsibilities.

(a) The Contracting Officer shall include the clause in 352.270–1 in every solicitation and resulting contract when the statement of work requires the contractor to conduct meetings, conferences, or seminars in accordance with 370.101(b).

(b) The Project Officer shall be responsible for obtaining, reviewing, and approving the contractor's plan, which is to be submitted in response to paragraph (a) of the contract clause in 352.270–1. A consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars will be acceptable. The Project Officer, prior to approving the plan, should consult with the OPDIV or other designated organization responsible for ensuring 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 Project Officer shall ask the responsible organization to review, and determine the adequacy of, the contractor's plan, and respond to the Project Officer, in writing, within ten (10) working days of receiving the request from the Project Officer.

■ 122. Amend section 370.205 by revising paragraph (a) to read as follows:

370.205 Tribal preference requirements.

(a) Where the work under a contract is to be performed on an Indian reservation, the contracting activity may supplement the clause set forth in 352.270–3 by adding specific Indian preference requirements of the Tribe on whose reservation the work is to be performed. The supplemental requirements shall be jointly developed for the contract by the contracting activity and the Tribe. Supplemental preference requirements must represent a further implementation of the requirements of section 7(b) of Public Law 93–638 and must be approved by the affected program director and approved for legal sufficiency by the General Law Division, OGC, or a regional attorney before being added to a solicitation and resultant contract. Any supplemental preference requirements to be added to the clause in 352.270–3 shall be included in the solicitation and clearly identified in order to insure uniform understanding of the additional requirements by all prospective bidders or offerors.

* * * * *

■ 123. Revise section 370.301 to read as follows:

370.301 Policy.

It is the policy of the Department of Health and Human Services (HHS) that no contract involving human subjects shall be awarded until acceptable assurance has been given that the activity will be subject to initial and continuing review by an appropriate Institutional Review Board (IRB) as described in HHS regulations at 45 CFR 46.103. An applicable Federalwide Assurance (FWA), approved by the HHS Office of Human Research Protections (OHRP), shall be required of each contractor, subcontractor, or cooperating institution having responsibility for human subjects involved in performance of the contract. The HHS OHRP is responsible for negotiating assurances covering all HHS-supported or HHS-conducted activities involving human subjects. OHRP shall guide Contracting Officers regarding nonaward or termination of a contract due to inadequate assurance or breach of assurance for protection of human subjects.

■ 124. Revise section 370.302 to read as follows:

370.302 Types of assurances.

(a) In January 2005, OHRP announced that the FWA would be the only new type of assurance accepted for review and approval by OHRP. Institutions holding an OHRP-approved Multiple Project Assurance (MPA) or Cooperative Project Assurance (CPA) were required to submit an FWA to OHRP for approval by December 31, 2005, if the institution is required to have an OHRP-approved assurance of compliance. Any Inter-Institutional Amendment between an OHRP-approved MPA and an affiliate institution will be deactivated on January 1, 2006 if the affiliate institution has not obtained its own FWA. Single Project Assurances (SPAs) currently approved by OHRP will remain in effect for the duration of the project and through all non-competitive award renewals. An FWA listed in OHRP's current ''List of Registered Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) and Approved Assurances'' is acceptable for the purposes of this policy. The list may be found at *http://ohrp.cit.nih.gov/search/asearch.asp.*

(b) The OHRP Web site includes links to instructions and the forms for submitting both a domestic and

international FWA at *http://www.hhs.gov/ohrp/assurances/assurances_index.html*. To expedite the approval of a FWA, as well as any update/renewal, the institution shall use the OHRP Electronic Submission System. Once an electronic file is ''submitted'' to OHRP, the institution must fax or mail (do not do both) a copy of the signature page to initiate the review process. FWAs shall be mailed to the OHRP, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852, or faxed to OHRP at 240–453–8202 (do not do both).

■ 125. Revise section 370.303 to read as follows:

370.303 Notice to offerors.

(a) Solicitations shall contain the notice to offerors in 352.270–8(a) whenever contract performance is expected to involve human subjects.

(b) IRB approval of proposals submitted by institutions having an OHRP-approved FWA should be certified in the manner required by instructions for completion of the contract proposal; or 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) FWAs for contractors, subcontractors, or cooperating institutions generally will not be requested prior to determination that a contract proposal has been selected for negotiation. When an FWA is submitted, 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 noncompetitive renewal proposal shall be certified in the manner described in the preceding paragraph.

■ 126. Revise section 370.401 to read as follows:

370.401 Policy.

(a) It is the policy of the Department of Health and Human Services (HHS) that no contract involving live vertebrate animals shall be awarded until acceptable assurance has been given that the activity will be 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. An applicable Full Animal Welfare Assurance or Interinstitutional Agreement/Assurance, approved by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), shall be required of each contractor, subcontractor, or cooperating institution having responsibility for animal care and use involved in performance of the contract (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 guide Contracting Officers regarding adequate animal care, and use, approval, disapproval, restriction, or withdrawal of approval of assurances (see PHS Policy V.A.).

■ 127. Revise section 370.402 to read as follows:

370.402 Assurances.

(a) Assurances may be one of two types:

(1) *Full Animal Welfare Assurance (AWA).* An AWA describes the institution's complete program for the care and use of animals, including but not limited to the facilities, occupational health, training, veterinary care, IACUC procedures and lines of authority and responsibility. An AWA listed in OLAW's list of institutions which have an approved full AWA will be considered acceptable for purposes of this policy.

(2) *Interinstitutional Agreement/Assurance (IAA).* An IAA describes the arrangements between an offeror and usually a subcontractor where animal activities will occur. An IAA is limited to the specific award or single project.

(b) The Contracting Officer shall forward copies of proposals selected for negotiation and requiring an assurance to the Assurance Branch, Office of Laboratory Animal Welfare (OLAW), NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible to secure the necessary assurances.

(c) A contractor providing animal care services at an assured entity, such as a Government-owned, contractor-operated (GOCO) site, does not need a separate assurance because the GOCO site normally covers the contractor services in the GOCO site assurance.

■ 128. Revise section 370.403 to read as follows:

370.403 Notice to offerors.

Solicitations shall contain the notice to offerors in 352.270–9(a) whenever contract performance is expected to involve the use of live vertebrate animals.

(a) For offerors having a full AWA on file with OLAW, IACUC approval of the use of animals shall be submitted in the manner required by instructions for completion of the contract proposal, but prior to the technical review of the proposal. The date of IACUC review and approval must not be more than 36 months prior to the deadline for proposal submission.

(b) Non-assured offerors are not required to submit assurances or IACUC approval with proposals. OLAW will contact contractors, subcontractors and cooperating institutions to negotiate necessary assurances and verify IACUC approvals when requested by appropriate HHS/PHS staff.

■ 129. Revise section 370.504 to read as follows:

370.504 Competition.

(a) Contracts awarded under the Buy Indian Act are subject to competition among Indians or Indian concerns to the maximum extent that the Contracting Officer determines is practicable. When competition is determined not to be practicable, a Justification for Other than Full and Open Competition shall be prepared in accordance with 306.303 and subsequently retained in the contract file.

(b) Solicitations must be synopsized and publicized in *FedBizOpps* at *http://www.fedbizopps.gov* and copies of the synopses sent to the tribal office of the Indian tribal government directly concerned with the proposed acquisition as well as to Indian concerns and others having a legitimate interest. The synopsis must state that the acquisition is restricted to Indian firms under the Buy Indian Act.

[FR Doc. E6–21505 Filed 12–19–06; 8:45 am]

BILLING CODE 4150–28–P