

**FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION**

**PROCUREMENT AND SUPPLY MANAGEMENT**

**REQUEST FOR CONTRACT FOR ACTIONS EXCEEDING THE SIMPLIFIED ACQUISITION THRESHOLD**

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**1. PURPOSE**

This guide sets forth the FDA policy and procedures for completion, approval, and submittal of a Request for Contract (RFC) – which, at a minimum, is comprised of a Requisition document, clear identification of the overarching and previously approved Acquisition Strategy (AS), Acquisition Plan (AP), and RFC Approval/Checklist Addendum – for contract actions with an estimated value (inclusive of all options) exceeding the Simplified Acquisition Threshold (SAT). It satisfies applicable *Federal Acquisition Regulation (FAR) Part 7 - Acquisition Planning requirements and implements Department of Health and Human Services (HHS) Acquisition Alert 2015-01: New Acquisition Guides and Templates, dated March 26, 2015*.

**NOTE:** This Guide does not address modification actions to pre-existing awards. For guidance and assistance executing award modifications, Program Personnel should contact the Office of Acquisitions and Grants Services (OAGS). The

<sup>1</sup> To access the Attachments 1, 2, and 3, please see the “Attachments” in the left window panel of the browser. The SMG Attachments are available via Microsoft Internet Explorer and Firefox Browsers only.

assigned OAGS Contracting Officer (CO)/Contract Specialist (CS) will provide all requisite guidance specific to each individual modification action.

## 2. DEFINITIONS

**Preliminary Disclosure:** *As a general rule, and unless indicated otherwise below, the FDA incorporates by reference, the definitions of words and terms adopted by HHS Policy and the FAR. Because HHS Policy may supplement the FAR and FDA Policy may further supplement HHS Policy, there may be some instances in which the definitions of words and terms may be more narrowly construed so as to accurately reflect the acquisition function at the Department or FDA levels. In those instances, FDA Policy shall take precedence over HHS Policy and HHS Policy shall take precedence over the FAR.*

- A. Acquisition Plan (AP): A plan that documents all cost, schedule, technical, business, management, and other considerations that will govern a specific acquisition and is derived from the acquisition strategy. It summarizes the acquisition planning discussions and identifies milestones in the acquisition process.
- B. Acquisition Planning: The process by which the efforts of all personnel responsible for an acquisition are coordinated and integrated through a comprehensive plan for fulfilling an agency need in a timely manner and at a reasonable cost. It includes developing the overall strategy for managing the acquisition.
- C. Acquisition Strategy (AS): A top-level description of an agency program or project to procure the necessary resources to satisfy an agency need. It provides sufficient detail to allow senior leadership and other decision makers to assess whether the strategy makes good business sense. An AS is meant to effectively implement laws and policies, and accurately reflect management's priorities. An individual AS typically serves as the foundation for the development of multiple Acquisition Plans supporting a specific program/project.
- D. Advance Acquisition Plan (AAP): An acquisition planning and tracking tool that identifies all FDA anticipated acquisition actions over \$25,000 (inclusive of all options) for a given fiscal year. The AAP is captured in the Integrated Budget and Acquisition Planning System (IBAPS). It is a compilation of all individually submitted FDA Center acquisition planning items that is regularly updated to capture changes on an ongoing basis. The AAP must provide a sufficiently clear and detailed description of each requirement (e.g., planned contract with any options, modification, delivery order, task order, purchase order, grant, interagency agreement) having an estimated value anticipated to exceed \$25,000 (inclusive of all options).

Upon creation of an AAP item in IBAPS, a Center Item Number is generated to uniquely identify each requirement on the plan.

- E. Contracting Officer (CO): An acquisition professional residing within OAGS who has the authority to enter into, administer, and/or terminate contracts and make related determinations and findings.
- F. Contracting Officer's Representative (COR): An acquisition workforce member residing within a Program Center/Office designated and authorized in writing by the Contracting Officer to perform specific technical or administrative functions for a specific contract. A COR does not have authority to bind the Government by signing a contract or otherwise entering into a contractual arrangement.
- G. Contract Specialist (CS): An acquisition professional residing within OAGS who has the authority to negotiate, administer, and close-out contracts, subject to the review and approval of the Contracting Officer. The CS advises the COR and serves as the primary Point of Contact throughout the acquisition process.
- H. Integrated Budget and Acquisition Planning System (IBAPS): A suite of applications that support budget formulation, budget execution, acquisition planning (to include the AAP), and payroll planning.
- I. iProcurement: One component of the HHS Unified Financial Management System (UFMS) that is managed by the Office of Financial Management at the FDA. iProcurement is a web-based application where FDA requisitions are entered, approved, and tracked on a real time basis. Designated Requestors/Requisitioners identify the appropriate funding information (Common Account Number 'CAN' and Object Class) for each line item when entering requisitions into iProcurement. The requisition is then routed through predefined approval chains that may be modified, as needed. Upon final approval, the iProcurement requisition creates a commitment record within UFMS.
- J. Non-severable Performance Requirements: Performance requirements that comprise an entire or nonrecurring undertaking that cannot be feasibly subdivided. They typically contemplate a specific outcome, product, or report. The agency does not receive the full value of a non- severable performance requirement until performance is fully completed. Full performance must have independent value (i.e., its value cannot depend upon the accomplishment of another activity). If full performance provides value only upon additional action, then the performance requirement is not non-severable and may represent only a portion of a non-severable performance requirement.

Non-severable performance requirements must be fully funded at time of award; however, they may take more than 12 months to complete (e.g., a study conducted over eighteen months that culminates in the delivery of a final report). Thus, non-severable performance requirements may not be incrementally funded. See *Incremental Funding of U.S. Fish and Wildlife Service Research Work Orders*, B-240264, 1994.

- K. Program: A group of assets planned and managed together to achieve an overall set of related outcomes. They are directed, funded acquisitions that provide new, improved, or continuing systems or services in response to an approved need. Programs are divided into levels established to facilitate decision-making, execution, and compliance with statutory and regulatory requirements and may be composed of multiple projects, services contracts, interagency agreements, and other types of acquisitions. With a systems or services capability focus, programs usually tie together an agency's higher-level programming and budgeting process with the agency strategic plan.
- L. Program Manager: An acquisition workforce member residing within a Program Center/Office who has the responsibility, and relevant discretionary authority, to make final scope-of-work, capital-investment, and performance acceptability decisions on assigned acquisition programs. The Program Manager is also responsible for meeting program objectives or production requirements through the acquisition of any mix of in-house, contract, or reimbursable support resources. Program Managers are responsible to stakeholders for management and oversight of subordinate projects within the scope of the overall program. The Program Manager is ultimately responsible for effectively managing all business and technical risks of the program to insure effective systems and services are delivered to the end user on schedule, within budget and at the required levels of performance. A Program Manager may also serve as a project manager and in this capacity will perform the responsibilities of the project manager.
- M. Project: An endeavor undertaken to accomplish a unique product or service with a defined start and end point and specific objectives that, when attained, signify completion. Projects are undertaken for development, modernization, enhancement, disposal, or maintenance. Projects are composed of activities and are planned acquisition undertakings with a definite beginning and clear termination point which produces a defined capability. A project is an individually planned, approved and managed basic building block related to a program.
- N. Project Advisory Group (PAG): Ordinarily, three or more persons designated by the sponsoring Center/Office to serve as an advisory and review body on technical matters during the acquisition process. The PAG is primarily responsible for evaluating technical proposals and cost

proposals, as appropriate. The Contracting Officer's Representative is responsible for planning, organizing, and convening meetings of the PAG.

- O. Project Manager: An acquisition workforce member residing within a Program Center/Office who has responsibility for accomplishing a specifically designated work effort or group of closely related efforts established to achieve stated or designated objectives, defined tasks, or other units of related effort on a schedule, within cost constraints and in support of the program mission or objective. The Project Manager is responsible for the planning, controlling, and reporting of the project, and for the management of required functions, including acquisition strategy and planning, defining requirements, business case development, performance of the schedule, and formulation, justification, and execution of the budget. The Project Manager is responsible for effectively managing project risks to insure effective systems and services are delivered through a total life-cycle approach to the end user on schedule, within budget and at the required levels of performance. A Program Manager may also serve as Project Manager for projects within the scope of the program.
- P. Property Administrator: An FDA program official responsible for – in cooperation with the FDA Accountable Property Management Office – barcoding, recording, tracking, and managing all aspects of Government Furnished Property to be provided to contractor(s) and subcontractor(s) under a contract or other award instrument/agreement.
- Q. Severable Performance Requirements: Requirements that can be separated into components that independently meet an ongoing need of the Government. They typically are continuing and recurring in nature. An agency receives the full value of the severable performance requirement every time it is performed (e.g., janitorial or security services).

The use of annual funds for severable performance requirements may cross fiscal years, but may not exceed twelve months. See *Funding of Maintenance Contract Extending Beyond Fiscal Year, B-259274, 1996*. On the other hand, the use of no-year funds (e.g., User Fees) for severable performance requirements, are not subject to the same twelve- month limitation. See *Severable Services Contracts, B-317636, 2009*.
- R. Simplified Acquisition Threshold (SAT): The threshold dollar amount, under which simplified acquisition procedures are authorized. See *FAR 2.101* for the current threshold dollar amount and applicable exceptions.
- S. Sponsor: The Center/Office having the specific acquisition requirement and responsible for the commitment of funds for the proposed contract.

- T. Unified Financial Management System (UFMS): UFMS is an integrated system allowing purchasing functions to flow directly to Accounts Payable and the General Ledger modules.

### **3. POLICY AND PROCEDURES**

#### **A. PREPARATION OF THE REQUEST FOR CONTRACT (RFC)**

The RFC serves as the official request for initiating a contract action in accordance with this guide. It should contain all preliminary documents, approvals, and authorizations for a planned contract action. It should also identify all administration details and provide funding commitment information. Absent a prior agreement to the contrary, Program Personnel (ordinarily a Program/Project Manager (P/PM) or an individual who will eventually serve as the Contracting Officer's Representative (COR)) must complete and submit a RFC to OAGS via iProcurement to formally initiate a specific contract action.

It is essential that Program Personnel proactively obtain all needed assistance from contributing members of the Greater FDA and HHS Acquisition Communities (e.g., acquisition, budget, finance, human resources, information technology, facilities, security, office of legal counsel, and program subject matter experts) as early as possible for guidance and assistance in completing all components of the RFC to ensure that Agency needs are met in a timely, efficient, and effective manner.

The RFC includes, at a minimum: a Requisition document which cites type and amount of available funds to support a given action; clear identification of the overarching and previously approved Acquisition Strategy (AS); an Acquisition Plan (AP); and, a completed RFC Checklist, to include a Severability & Funding Determination and all other requisite attachments. When entering a requisition, Centers must enter the Center Item Number (CIN) reflected in their Advance Acquisition Plan (AAP) in the iProcurement Requisition 'AAP Number' field. AS, AP, and RFC Checklist requirements are addressed below in Sections 3.B. through 3.D., respectively.

#### **B. THE ACQUISITION STRATEGY (AS).**

##### **1. Use of the HHS AS Template Is Mandatory for all Programs/Projects.**

An AS is required for all Programs/Projects (P/Ps) -- irrespective of estimated aggregate value or duration, if it is to be supported by one or more procurements. The AS must be completed using the prescribed

HHS Template. The HHS AS Template and instructions for its completion, along with the overarching *Directive for Acquisition Strategy (DFAS)*, are currently available on the HHS/Office of Grants and Acquisition Policy and Accountability (OGAPA) Intranet Site. The current link is available at <https://hhsgov.sharepoint.com/sites/HHSAP/SitePages/HHSAM-Appendices-Guides-Templates.aspx>.

## **2. Program Personnel Are Responsible for Completion of the AS.**

Program Personnel (ordinarily P/PMs) are responsible for completing the AS prior to the development of milestones to addresses the critical elements of the Program/Project (P/P). The AS includes information relevant to: management approach, business strategy, risks, technology, resources, requirements roadmap, procurement forecasting, testing, training, milestone schedules, implementation phases, and other logistics support over the entire P/P life cycle.

## **3. Assistance is Available to Help Program Personnel Complete the AS.**

### **a. Contact OAGS for Help Completing an AS that is < \$20M.**

In the event Program Personnel require any guidance or assistance in completing the HHS AS Template for a P/P with an estimated value less than \$20 Million (and not determined to be High Risk in accordance with the HHS DFAS), Program Personnel should contact OAGS at [askOAGS@fda.hhs.gov](mailto:askOAGS@fda.hhs.gov). When e-mailing such requests, Program Personnel shall place in the e-mail subject line, “Request for BMT AS Support for (*insert name of AS Program/Project or other identifier*).”

### **b. Contact HHS for Help Completing an AS that is > \$20M or High Risk.**

In the event Program Personnel require any guidance or assistance in completing the HHS AS Template for a P/P with an estimated value greater than or equal to \$20 Million (or, otherwise determined to be High Risk in accordance with the HHS DFAS), Program Personnel should contact HHS/Office of Grants and Acquisition Policy and Accountability (OGAPA)/Division of Acquisition (DA)/Office of Acquisition Workforce and Strategic Initiatives (OAWSI) at [OGAPA@hhs.gov](mailto:OGAPA@hhs.gov).

**NOTE:** After obtaining any requisite assistance from HHS, Program Personnel will still need to coordinate efforts with OAGS and all other requisite Agency-level signatories to obtain concurrence and approval of each individual AS prior to

HHS submittal for final approval. It should be understood that FDA Approving Officials – to include the Head of the Contracting Activity (HCA) – are required to leverage independent experience, knowledge, and business judgment in their official capacities when reviewing an AS prior to approval. That being stated, there may be instances in which some signatories will require that some portions of the AS be enhanced prior to their approval even in those instances in which HHS-level guidance and support has already been provided.

#### **4. HHS-level Approvals Are Required for an AS that is > \$20M or High Risk.**

In addition to all Program/Center approvals, if the aggregate total estimated value of an AS is less than \$20 Million (and not determined to be High Risk in accordance with the HHS DFAS), it will require approval by the FDA/OAGS Head of the Contracting Activity.

And, if the aggregate total estimated value of the AS is greater than or equal to \$20 Million (or, otherwise determined to be High Risk in accordance with the HHS DFAS), it will require HHS-level approvals by the Director, Office of Small and Disadvantaged Business Utilization (OSDBU) and Senior Procurement Executive (SPE). Further, if any IT goods or services will be needed, then additional approval by the HHS Chief Information Officer (CIO) will be required.

Whenever HHS-level approvals are required for an AS, Program Personnel will also need to complete a PowerPoint Presentation. The completed draft PowerPoint shall accompany the AS at time of HHS AS submittal. See Chapter 4 of the HHS DFAS, the AS Template, and the clarifications provided below for a complete list of requirements and approvals.

#### **5. HHS AS Template Signature Block Clarifications.**

It should be understood that not all listed signatories on the HHS AS Template reflect mandatory approvals for each and every AS. For example, Division and HHS CIO approvals are only required when IT goods or services will be needed. In those instances where it is clear that a listed approval is not required, marking the signature block as “Not Applicable” is acceptable. It is also important to understand to whom the listed signatories refer at the FDA. For that reason, the following clarifications are provided for each listed signatory block listed on Pages 3-5 of the HHS AS Template:

- a. FDA Signatories

- (1) Program Manager: the cognizant Program or Center Certified P/PM
- (2) Division Chief Information Officer (Division CIO): the FDA CIO
  - (required only if IT goods or services will be needed)
- (3) Division Head or Designee: the cognizant FDA Center/Office Senior Executive
- (4) Division Office of Small and Disadvantaged Business Utilization (OSDBU) Representative: the FDA OSDBU Representative located within OAGS
- (5) Head of Contracting Activity (HCA): the FDA HCA/Director, OAGS

b. HHS Signatories

- (1) Chief Information Officer (CIO): the HHS CIO (required only if IT goods or services will be needed)
- (2) Director, Office of Small and Disadvantaged Business Utilization (OSDBU) Representative: the HHS OSDBU Director
- (3) Senior Procurement Executive (SPE): the HHS SPE/Associate Deputy Assistant Secretary, Division of Acquisition

**6. AS Review and Approvals Will Impact Standard Procurement Lead Times.**

After the AS has been presumed complete, has all other requisite FDA-level approvals, and is ready for formal HCA submittal, Program Personnel shall upload the AS (along with a copy of the AS PowerPoint Presentation, if applicable) to the OAGS Acquisition Strategy SharePoint Site, located at <mailto:askoags@fda.hhs.gov>. Upon posting, the requisite OAGS Officials will automatically be notified that your submittal has been received.

The estimated turnaround time for OAGS to complete AS reviews is no more than 3-7 business days. In the event any changes are required, OAGS will contact the cognizant Program point of contact to provide any feedback and ensure that progress continues to move forward in a

linear and timely manner. In the event that HHS-level approval is required (i.e., the AS has an estimated value greater than or equal to \$20M (inclusive of all options), or is otherwise determined to be High Risk), the HCA will forward any HCA-approved AS to HHS on behalf of the cognizant Program/Project point of contact.

HHS has recommended that FDA Officials plan for a 30-calendar-day turnaround time for HHS to complete a comprehensive review of an AS. While the standard time for HHS review and approval is ordinarily expected to take 3-7 business days, there are many factors (e.g., thoroughness and quality of the AS submittal; competing demands) that will impact the duration of such reviews. If HHS determines, upon initial review, that further information is required, or that corrections need be made, HHS will attempt to notify the Program Office point of contact within 3 business days. Should such action be necessary, the cycle will start over again; and, upon receipt of any ensuing resubmittal, HHS will require an additional 3-7 business days to complete a follow-on review.

Once preliminarily approved by the HHS Senior Procurement Executive (SPE), the SPE will schedule a Review Board Panel Meeting (with a Board comprised of Department-wide Executive-level subject matter experts) for the FDA Program Officials to present their AS PowerPoint Presentation. Upon successful completion of the subject presentation, the Board will grant final approval of the AS.

**NOTE:** No Waivers for HHS AS review and approval will be granted.

Program Personnel are highly encouraged to make every attempt to complete each AS completely and accurately prior to initial submittal for review and approval by required signatories (including, but not limited to those at HHS), well in advance of applicable standard procurement lead times for individual contract actions.

## **7. Major Revisions to an Approved AS May Result in Further Delays.**

Each AS must be updated whenever there is a change to the approved strategy or as the approach and P/P elements are better defined. Major revisions to the AS shall be approved at the original approval levels. Once approved, the AS provides a basis for more detailed planning, to include the development, review and approval of individual Acquisition Plans for new procurements anticipated to support program initiatives and activities within scope of the overarching AS.

## **C. THE ACQUISITION PLAN (AP).**

## **1. Use of the HHS AP Template Is Mandatory Over the SAT.**

An AP is required for all new procurements with an estimated value (inclusive of all options) exceeding the Simplified Acquisition Threshold (SAT). The AP must be completed using the prescribed HHS Template. The HHS AP Template and instructions for its completion, along with the overarching *HHS Directive for Acquisition Planning (DFAP)*, are currently available on the HHS/OGAPA Intranet Site. The current link is available at <https://hhsgov.sharepoint.com/sites/HHSAP/SitePages/HHSAM-Appendices-Guides-Templates.aspx>.

### **a. Use of the FDA-specific Milestone Plan Template Is Mandatory.**

The FDA does not use the HHS Milestone Chart Template found at Appendix B of the HHS DFAP. OAGS has developed an FDA- specific Milestone Plan Template (available for download on the OAGS SharePoint Site, located at <https://fda.sharepoint.com/sites/insideFDA-OC-OO-OFBA-OAGS/SitePages/ALP.aspx>) and will work directly with Program Personnel to ensure that it is properly formulated to meet acquisition needs and objectives in a timely, realistic, and appropriate manner.

### **b. Use of the HHS IGCE Template Is Highly Encouraged.**

While the use of alternate Independent Government Cost Estimate (IGCE) formats is generally acceptable (to the extent that all estimated cost factors are completely addressed, documented, and supported), use of the HHS IGCE Template is highly encouraged. The HHS IGCE Template and instructions for its use, along with an array of helpful resources, are available on the HHS/Office of Grants and Acquisition Policy and Accountability (OGAPA) Intranet Site. The current link is available at <https://hhsgov.sharepoint.com/sites/HHSAP/SitePages/HHS-OAP-Templates.aspx>. In addition, alternate IGCE templates are available for download on the OAGS SharePoint Site, located at <http://sharepoint.fda.gov/orgs/OC-OO-OFBA/apob/Pages/OAGS-Active-Forms-and-Templates.aspx>.

## **2. Program Personnel Are Responsible for Completion of the AP.**

Program Personnel (ordinarily P/PMs or CORs) are responsible for completing the AP with input from the entire acquisition team. Every AP must relate back to and fall under an approved AS. Acquisition planning should start as soon as the AS is approved, preferably well in

advance of the fiscal year in which contract award or order placement is necessary. The AP should address the technical, business, management, and other significant considerations that will affect the acquisition lifecycle. The specific content of each plan will vary depending on the nature, circumstances, and complexity of the action.

**3. Program Personnel Are to Contact OAGS to Obtain any Requisite Assistance.**

Program Personnel are highly encouraged to seek OAGS assistance as early as possible during the acquisition planning process to obtain any requisite guidance or assistance in completing the AP to foster the successful execution of all actions in a timely, effective, and efficient manner. In order to request any such assistance, Program Personnel shall contact the OAGS Division Director with cognizance or purview over their specific acquisition. In the event Program Personnel do not know which OAGS Division Director to contact, Program Personnel shall send an e-mail request for assistance to [askOAGS@fda.hhs.gov](mailto:askOAGS@fda.hhs.gov) with "Request for AP Assistance for (insert name of the requirement or other identifier)" in the subject line. Program Personnel should not ordinarily contact HHS directly to seek guidance, assistance, or approval of any AP. OAGS will coordinate any necessary HHS communication and approval requirements specific to each AP.

**4. Both FDA and HHS-level Approvals May Be Required.**

In addition to all Program/Center approvals, there are other Acquisition Plan approval requirements that correspond with the aggregate, estimated value of each AP (inclusive of all options), as follows:

- a. < \$5M – the cognizant OAGS Contracting Officer; and
- b.  $\geq$  \$5M but < \$20M – the cognizant OAGS Division Director; and
- c.  $\geq$  \$20M – the FDA/OAGS HCA [HCA to send an approved AP copy to HHS]; and
- d.  $\geq$  \$50M – the HHS SPE [HCA will forward directly to HHS for approval].

As indicated above, in the event the aggregate total estimated value of the AP (inclusive of all options) is greater than or equal to \$50M, it will require HHS-level approval by the Senior Procurement Executive (SPE). The SPE may also require approval by the Director, Office of Small and Disadvantaged Business Utilization (OSDBU); the Department Competition Advocate; the Department

Chief Information Officer (only when IT or IT-related Goods/Services are required); and/or, the Office of General Counsel. Please see the HHS DFAP and AP Template for a complete list of requirements and approvals.

**5. AP Review and Approvals Will Impact Standard Procurement Lead Times.**

While the standard time for HHS review and approval is ordinarily expected to take no more than 3-7 business days, there are many factors (e.g., thoroughness and quality of the AP submittal; competing demands) that will impact the duration of such reviews. If HHS determines, upon initial review, that further information is required, or that corrections need be made, HHS will attempt to notify the HCA within 3 business days. Should such action be necessary, the cycle will start over again; and, upon receipt of any ensuing resubmittal, HHS will require an additional 3-7 business days to complete the follow-on review.

**NOTE:** No Waivers for HHS AP review and approval will be granted.

Program Personnel are highly encouraged to make every attempt to complete each AP completely and accurately prior to initial submittal for review and approval by required signatories, well in advance of applicable standard procurement lead times for individual contract actions.

**6. Major Revisions to an Approved AP May Result in Further Delays.**

Each AP must be updated whenever there is a change to the approved plan. Major revisions to the AP shall be approved at the original approval levels. Once approved, the AP provides a basis to begin the development and eventual release of a solicitation for new procurements.

**7. HHS AP Template Signature Block Clarifications.**

It should be understood that not all listed signatories on the HHS AP Template reflect mandatory approvals for each and every AP. For example, Office of the General Council (Legal) approvals are only required when an issue of law has been identified by any member of the acquisition team that requires formal legal opinion, guidance, or resolution. In those instances where it is clear that a listed approval is not required, marking the Box next to the signatory line for "N/A" is acceptable. It is also important to understand to whom the listed signatories refer at the FDA. For that reason, the following clarifications

are provided for each listed signatory block listed on Page 11 of the HHS AP Template:

- a. Funds Certifying Official: the cognizant FDA Budget Officer
- b. Requiring Activity Representative: the FDA Program/Center Requisitioner (ordinarily, that same individual will eventually serve as the Contracting Officer's Representative (COR) for any resultant award, if a COR is required)
- c. Requiring Activity Representative's Immediate Supervisor: the FDA Program/Center Requisitioner's Immediate Supervisor
- d. Program Manager: the FDA Program/Center P/PM (ordinarily, that same individual has purview over the AS that serves as the overarching foundation for development of the subject AP)
- e. Head of the Sponsoring Program Office: the FDA Program/Center P/PM's immediate supervisor
- f. Contracting Officer: the cognizant OAGS Contracting Officer
- g. Chief of the Contracting Office: "Not Applicable" (See SMG Section 3.C.(4) for other OAGS Approving Official requirements)
- h. Office of the General Council (Legal): HHS Office of General Council, as required (See SMG Section 3.C.(7), First Paragraph, for further guidance)
- i. Head of the Contracting Activity: the FDA HCA/Director, OAGS
- j. Competition Advocate: the FDA Competition Advocate (only required for certain Non-Competitive Awards; the cognizant OAGS CO will be able to provide all requisite guidance as to when/if such approval is required)
- k. HHS Senior Procurement Executive: the HHS SPE/Associate Deputy Assistant Secretary, Division of Acquisition

#### **D. THE RFC CLEARANCE/APPROVAL CHECKLIST ADDENDUM.**

A completed RFC Clearance/Approval Checklist (RFC Checklist) is required for every new RFC submitted to OAGS for processing.

Completion of the RFC Checklist will require substantial time, attention, and effort for its proper completion. The purpose of the RFC Checklist is threefold: (1) it provides reassurance that certain procurement-specific analyses, determinations, and approvals are identified and executed to meet applicable statutory, regulatory, policy, and programmatic requirements; (2) it provides advance notice to Program Officials that any applicable analyses, determinations, and approvals – if not properly completed at time of RFC submittal – may likely impact procurement processing lead times, to include possible delays in the release of a solicitation and the prospective award of a contract or order; and (3) it serves as a roadmap for OAGS Contracting Officers/Contract Specialists to ensure that the necessary approvals and safeguards are executed, and that the prospective award contains appropriate contract language to address programmatic requirements while minimizing risk to the Government.

The P/PM is responsible for ensuring all applicable pre-solicitation and pre-award clearances/approvals that apply to a given procurement are accurately identified and addressed by checking the appropriate block(s) on the RFC Checklist. The P/PM is also responsible for providing the requisite analyses, determinations, and approvals as attachments to the RFC Checklist, or otherwise indicating when any missing or incomplete documentation will be provided. The RFC Checklist is not exhaustive and may not list all required clearances and approvals for a specific procurement. For that reason, Block 19 of the RFC Checklist is a catch-all item to for P/PMs to list other known clearances and approvals.

Program Personnel are highly encouraged to seek OAGS assistance as early as possible during the acquisition planning process to obtain any requisite guidance or assistance in completing the RFC Checklist to ensure all actions are processed in a timely, effective, and efficient manner. In order to request any such assistance, Program Personnel shall contact the OAGS Division Director with cognizance or purview over their specific acquisition. In the event Program Personnel do not know which OAGS Division Director to contact, Program Personnel shall send an e-mail request for assistance to [askOAGS@fda.hhs.gov](mailto:askOAGS@fda.hhs.gov) with “Request for RFC Checklist Assistance for (insert name of the requirement or other identifier)” in the subject line.

The RFC Checklist must be approved, signed, and dated by the cognizant Center P/PM responsible for management and oversight responsibilities over each individual contract to be awarded in support of the P/P under her/his purview. The P/PM signing the RFC Checklist should ordinarily be the same P/PM who approves the overarching AS and AP.

## **1. A Severability & Funding Determination Is Always Required.**

There is only one item on the RFC Checklist -- Item 1, Severability & Funding Determinations – that is checked by default because it is always required. The way in which a performance requirement is categorized (i.e., Severable or Non-Severable) is highly determinative of the way in which the corresponding award must be funded. Awards that are not properly funded may violate the Anti-Deficiency Act and result in serious repercussions for the FDA, as well as the individual employees who are held responsible. For that reason, a Determination – using the *Severability & Funding Determination Template* found at RFC Checklist Attachment 3.D.(1) – is mandatory for all contract actions exceeding the SAT.

#### **4. REFERENCES**

FDA Plan to Increase Access to Results of FDA-Funded Scientific Research, February 2015

FDA Staff Manual Guide 1440.1, December 24, 2009

Federal Acquisition Regulation Parts 2; 3; 6; 7; 8; 9; 11; 22; 23; 27; 37; 45

Federal Information Technology Acquisition Reform Act (FITARA), December 2014

Funding of Maintenance Contract Extending Beyond Fiscal Year, B-259274, 1996

HHS APM 2011-02, HHS' Prospective Service Acquisition Reviews, June 3, 2011

HHS APM 2011-03, Project Labor Agreements, July 25, 2011

HHS APM 2011-04, Appropriations Law Compliance Reviews, October 6, 2011

HHS APM 2011-05, Sustainable Green Acquisition, October 7, 2011

HHS Acquisition Regulation Parts 303; 304; 307; 315; 339; 370

HHS Acquisition Alert 2015-01: New Acquisition Guides and Templates, March 2015

HHS Directive for Acquisition Strategy, March 2015

HHS Directive for Acquisition Planning, updated April 2015

HHS Independent Government Cost Estimate, March 2015

HHS Memorandum to OMB, Precision Medicine Initiative Privacy and Security Response Plan, dated circa December 2016

HHS Policy on Promoting Efficient Spending, January 23, 2015

HHS Security and Privacy Language for Information and Information Technology Acquisitions Guide (to be released circa March 2017)

Incremental Funding of U.S. Fish and Wildlife Service Research Work Orders, B-240264, 1994

OMB Circular A-108, Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act, reissued December 23, 2016.

OMB Circular A-130, Managing Federal Information as a Strategic Resource, revised July 27, 2016

OMB Memorandum 17-02, Precision Medicine Initiative Privacy and Security, dated October 21, 2016

Public Health Service Policy on Humane Care & Use of Laboratory Animals, revised 2015

## 5. EFFECTIVE DATE

This guide is effective February 27, 2017.

## 6. Document History - SMG 2610.1, Request for Contract for Actions Exceeding the Simplified Acquisition Threshold

STATUS (I,R,C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/01/2009	N/A	OC/OO/OM/ OSS/OAGS	Glenda Barfell, Director, OAGS
Change	06/04/2009	Sect. 3B	OC/OO/OM/ OSS/OAGS	Glenda Barfell, Director, OAGS
Revision	08/12/2011	N/A	OC/OO/OM/ OSS/OAGS	Glenda Barfell, Director, OAGS
Revision	02/21/2017	N/A	OC/OO/OM/ OSS/OAGS	Leonard Grant, Acting Director, OAGS
Change	03/21/2017	Links in Sect.3.B.6. and 3.C.1.	OC/OO/OM/ OSS/OAGS	Leonard Grant, Acting Director, OAGS
Change	09/11/2019	Add footnote 1	OC/OO/OM/ OSS/OAGS	Leonard Grant, Acting Director, OAGS

STATUS (I,R,C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Change	06/24/2025	Addendum 3.D. page 3, URL	OC/OO/OM/ OSS/OAGS	Daniel Feldman, Procurement Analyst, OAGS/DPSPS/APOB
Change	07/18/2025	Updated URLs pp. 7, 9, 11	OC/OO/OM/ OSS/OAGS	Daniel Feldman, Procurement Analyst, OAGS/DPSPS/APOB

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## Severability & Funding Determination

**Purpose:** This document provides the template for completing a Severability Determination to ensure funded contract actions executed by the FDA meet applicable fiscal law and acquisition policy requirements.

**REFERENCE CENTER ITEM NUMBER:** [Reference Item Number]

**REQUIREMENT TITLE/DESCRIPTION:** [Title/Description]

**REQUISITION NUMBER:** [Requisition Number]

The way in which a performance requirement is categorized (i.e., Severable or Non-Severable) is highly determinative of the way in which the corresponding award must be funded. Awards that are not properly funded may violate the Anti-Deficiency Act and result in serious repercussions for the FDA, as well as the individual employees who are held responsible.

**Non-Severable Performance Requirements:** Requirements that, from the time performance begins to the time it ends, constitutes a single, indivisible undertaking from which the requesting agency obtains no benefit until the entire undertaking has been completed. They typically require delivery of a specified end product (e.g., a final research report). Non-severable performance requirements must be fully funded at the time of award execution; however, they may take more than 12 months to complete. Thus, non-severable performance requirements may not be incrementally funded. See *Incremental Funding of U.S. Fish and Wildlife Service Research Work Orders*, B-240264, 1994.

**Severable Performance Requirements:** Requirements that are continuing and recurring in nature and can be separated into components that independently meet a need of the Government. The use of annual funds for severable performance requirements may cross fiscal years, but may not exceed twelve months. See *Funding of Maintenance Contract Extending Beyond Fiscal Year*, B-259274, 1996.

**Section I: Severability Determination.**

*(To be completed by Program Personnel.)*

- The subject performance requirements are Severable.
- The subject performance requirements are Non-Severable.

**Rationale:**

[Describe the characteristics of this requirement that support the severability determination.]

**Section II: Proposed Funding Approach.***(To be completed by Program Personnel.)*

- The prospective award will be funded in its entirety at time of award.
- The prospective award will leverage the use of options, each of which will be funded in its entirety at time of award.
- The prospective award will be incrementally funded within one or more periods of performance.

**Details/Further Information:**

[Provide any requisite details or information to explain the funding approach.]

**Section III: Type and Source of Funds to Be Used.***(To be completed by Program Personnel.)*

- The prospective award will be funded using one-year funds.
- The prospective award will be funded using multi-year funds.
- The prospective award will be funded using no-year funds.
- The prospective award will be funded using multiple types of funds.
- Fiscal Year of Funds to be used: \_\_\_\_\_.

**Details/Further Information:**

[Provide any requisite details or information to further explain the type and source of funds to be used – to include their fiscal year of origin.]

**Section IV: Program Certification.***(To be completed by Program Personnel.)*

- I hereby certify that, to the best of my knowledge and belief, the above information provided at Sections I – III is accurate and complete.
- I hereby certify that, to the best of my knowledge and belief, the subject funding approach complies with applicable fiscal law (e.g., Anti-Deficiency Act) and acquisition policy requirements.
- I understand and agree that, if any change in circumstances should take place that impact any of the determinations above, that I am required to complete a “New” Severability and Funding Determination.

**COMPLETED BY:**

(Insert Signature)

(Insert Date)

---

(Insert Printed Name of Program Official)

Date

(Insert Official Title and Center)

**Section V: Funding Certification.**

*(To be completed by the cognizant Funding Official.)*

Based upon my review of the information provided above at Sections I-IV, and in exercising my own professional judgment, I hereby certify that:

- I have no knowledge of or reason to believe that any of the above information provided at Sections I-IV is incorrect, incomplete, or otherwise requires revision.
- The subject funding approach complies with applicable fiscal law (e.g., Anti-Deficiency Act) and acquisition policy requirements.
- I understand that if I have any concerns regarding any of the information provided herein, I am required to fully address those concerns below.

**Concerns/Comments/Further Information:**

[Provide requisite details about any concerns or comments regarding the subject severability determination, proposed funding approach, type of funds to be used – to include the availability of such funding.]

**COMPLETED BY:**

(Insert Signature)

(Insert Date)

---

(Insert Printed Name of Program Official)  
(Insert Official Title and Center)

Date

**Section VI: Contracting Officer Determination.**

*(To be completed by the cognizant Contracting Officer.)*

Based upon my review of the information provided above at Sections I-V, and in exercising my own professional judgment, I hereby determine that:

- I have no knowledge of or reason to believe that any of the above information provided at Sections I-V is incorrect, incomplete, or otherwise requires revision.
- The subject severability determination, proposed funding approach, and type and source of funds to be used complies with applicable fiscal law (e.g., Anti-Deficiency Act) and acquisition policy requirements.
- The subject severability determination, proposed funding approach, and type and source of funds to be used does NOT comply with applicable fiscal law (e.g., Anti-Deficiency Act) and acquisition policy requirements. See comments below.

**Concerns/Comments/Further Information:**

[Provide requisite details about any concerns or comments regarding the subject severability determination, proposed funding approach, type of funds to be used – to include the availability of such funding.]

**APPROVED BY:**

(Insert Signature)

(Insert Date)

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(Insert Printed Name of Contracting Officer)      Date  
(Insert Official Title and Office)

## **Federal Information Technology Acquisition Reform Act (FITARA)**

### **Summary Approval Guidelines**

**Purpose:** *This document provides the FDA approval framework for Acquisition Strategies and Acquisition Plans with an IT Goods or Services Component under FITARA.*

FITARA Provides enhanced authorities to the HHS CIO and FDA CIO, through delegated authorities.

**The FDA CIO is authorized to:**

- Review and approve IT budgets, investments < \$20 Million annually or \$100 Million over 5 years, and acquisition strategies
- Approve the FDA IT budget request to the Department
- Conduct IT Portfolio Reviews for the IT budget

### **ACQUISITION STRATEGIES & PLANS WITH IT GOODS OR SERVICES**

*I. FDA Centers/Offices (includes OIMT and excludes OC)*

Acquisition Strategy Threshold*	FDA Concurrence	FDA Approval	Requires HHS Approval
<\$20M	Center/Office ITIRB	FDA CIO	No
>/=\$20M or High Risk	Center/Office ITIRB	FDA CIO	Yes
>/=\$100M over 5 years	Center/Office ITIRB	FDA CIO	Yes

Acquisition Plan Threshold*	FDA Concurrence	FDA Approval	Requires HHS Approval
<\$5M	Center/Office ITIRB	ADCIO (or equivalent)	No
>/=\$5M but <\$50M	ADCIO (or equivalent)	FDA CIO	No
>/=\$50M	ADCIO (or equivalent)	FDA CIO	Yes

*\*Threshold applies to the aggregate total estimated value unless otherwise noted.*

*II. Office of the Commissioner Only (excludes OIMT)*

Acquisition Strategy Threshold*	FDA Concurrence	FDA Approval	Requires HHS Approval
<\$20M	Relevant Deputy Commissioner and OC Executive Officer	FDA CIO	No
>/\$20M or High Risk	Relevant Deputy Commissioner and OC Executive Officer	FDA CIO	Yes
>/\$100M over 5 years	Relevant Deputy Commissioner and COO	FDA CIO	Yes

Acquisition Plan Threshold*	FDA Concurrence	FDA Approval	Requires HHS Approval
<\$5M	Super Office POC or SMO	ADCIO	No
>/\$5M but <\$50M	ADCIO (or equivalent)	FDA CIO	No
>/\$50M	ADCIO (or equivalent)	FDA CIO	Yes

\* Threshold applies to the aggregate total estimated value unless otherwise noted.

**NOTE:**

- Center/Office without an ITIRB will leverage the Business Subcommittee for FDA IT Concurrence on Acquisition Strategies
- All IT investments supported by one or more procurements must have an Acquisition Strategy
  - An Acquisition Strategy can address multiple IT investments
  - An IT investment can only be addressed in one Acquisition Strategy
- FDA CIO will review and approve Acquisition Plans for contracts that vary from an approved Acquisition Strategy
- All IT Requisitions must have an approved Acquisition Plan

**RFC Clearance/Approval Checklist**

*Source Selection Information – see FAR 2.101 and 3.104*

**Completion Instructions:** Complete the fill-ins below to identify the applicable Center Item Number (CIN), requirement title or description, and requisition number. Identify all unique considerations and clearances that apply to the subject procurement by checking the appropriate block(s) and attaching all requisite analyses, determinations, and approvals.

**REFERENCE CENTER ITEM NUMBER:** [Reference Item Number]

**REQUIREMENT TITLE/DESCRIPTION:** [Title/Description]

**REQUISITION NUMBER:** [Requisition Number]

**1. Severability & Funding Determination.** (Always Applicable)

The way in which a performance requirement is categorized (i.e., Severable or Non-Severable) is highly determinative of the way in which the corresponding award must be funded. Awards that are not properly funded may violate the Anti-Deficiency Act and result in serious repercussions for the FDA, as well as the individual employees who are held responsible.

A Severability & Funding Determination – using the Template provided herein as **Attachment 1** – is mandatory for all contract actions exceeding the SAT. Certain FDA Officials are required to complete each respective section of the Determination that falls under their purview, as follows:

- (a) Program Personnel: Sections I-IV
- (b) The cognizant Funding Official: Section V
- (c) The cognizant Contracting Officer: Section VI

**2. Advisory and Assistance Services for Evaluation of Proposals.**

Certain limitations apply and special considerations must be made before a solicited proposal may be disclosed outside the Government to a contractor or a contractor employee for evaluation purposes. See *FAR Subpart 37.2 and HHSAR 315.305*.

**3. Animal Welfare.**

Certain safeguards apply to protect animals involved in research, research training, biological testing, housing and maintenance, and

other activities involving live vertebrate animals under a contract. Prospective contract awardees are required to provide assurance that it understands and agrees to provide covered services subject to initial and continuing review by an appropriate Institutional Animal Care and Use Committee (IACUC). The Contracting Officer shall require an applicable Animal Welfare Assurance approved by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), from each contractor, subcontractor, or institution having responsibility for animal care and use involved in performance of the contract. See *the Public Health Service Policy on Humane Care and Use of Laboratory Animals, revised 2015, and HHSAR Subpart 370.4.*

**4. Conferences and Meeting Space.**

Heightened scrutiny applies to the expenditure of funds for conferences, meeting space, retreats, seminars, symposia or events that involve attendee travel. The term "conference" also applies to training activities that are considered to be conferences under 5 CFR 410.404.

The following approval thresholds apply, and must be complied with prior to the obligation of funds, for certain expenses related to conferences hosted directly by the FDA, sponsored by the FDA (e.g. through funding or a grant, cooperative agreement, interagency agreement, or co-sponsorship agreement), or attended by FDA staff (e.g. conferences hosted by another HHS OPDIV or STAFFDIV, Federal Agency, or non-Federal organization):

- (a) Less than \$100,000: Sponsoring Center/Office Executive Officer
- (b) \$100,000 to \$500,000: The FDA Chief Operating Officer
- (c) Greater than \$500,000: The FDA Commissioner (non-delegable).

See *HHS Policy on Promoting Efficient Spending - 1. Use of Appropriated Funds for Conferences and Meeting Space*, updated and reissued January 23, 2015, for a complete description of covered conference expenses and list of exceptions.

**5. Contracts with Federal Employees.**

Generally, the FDA shall not knowingly award a contract to a Government employee, business concern, or other organization -- that is owned, substantially owned, or controlled by one or more Government employees.

Any exception to this policy must be approved in advance by the Director, OAGS (non-delegable). See *FAR Subpart 3.6 and HHSAR Subpart 303.6*.

**6. Electronic and Information Technology – Section 508 Compliance.**

Electronic and information technology (EIT) supplies and services must comply with Section 508 of the Rehabilitation Act (the Act) of 1973 (29 U.S.C. 794d). See *HHSAR Subpart 339.2*.

**Note:** Covered solicitations shall include a separate technical evaluation factor specifically addressing Section 508 requirements. Solicitations for supplies and services shall require the submission of a Section 508 Product Assessment Template, currently available at <https://www.hhs.gov/web/section-508/acquisition-requirements/index.html>

**Note also:** Prior to making an award decision, the Contracting Officer/Contract Specialist shall forward the Source Selection Evaluation Team (SSET) assessment of the prospective offeror's responses to the solicitation's Section 508 evaluation factor to the FDA Section 508 Official or designee for review and approval.

**7. Food and Beverages.**

Generally, the FDA shall not use appropriated funds (whether from an annual appropriation, multi-year appropriation, appropriated user fee, mandatory appropriation, gift funds, or reimbursements from such appropriations, etc.) to purchase food (whether for conferences or meetings; for meals, light refreshments, or beverages; or for Federal or non-Federal participants), subject to certain, delineated exceptions and approvals. See *HHS Policy on Promoting Efficient Spending - 2. Use of Appropriated Funds for Food, issued January 3, 2012*.

**8. Government Furnished Property (GFP).**

The Government shall provide property to contractors only when it is clearly demonstrated that: (1) it is in the best interest of the Government; (2) the overall benefit to the acquisition significantly outweighs the increased cost of administration, including ultimate property disposal; (3) the assumption of risk to the Government will not be substantially increased if the property is provided; and (4) the Government requirements cannot otherwise be met.

In the event GFP will be provided to a contractor, an individual need be identified in the contract to serve as the FDA Property Administrator.

See *FAR Part 45* and FDA-specific acquisition policy for more information.

- 9. Information Security, Non-Disclosure Agreements, and Privacy.**
  - 9.1 Security and Privacy Language for Information & IT Acquisitions.**

Covered procurements are those under which contractor personnel (and/or any subcontractor) are expected to have: (a) routine physical access to an HHS-controlled facility; (b) logical access to an HHS-controlled information system; or (c) any access to federal information that may be sensitive, whether in an HHS-controlled information system or in hard copy; or (d) any combination of circumstances (a) through (c) above.

In regards to the procurement of **cloud services**, an acquisition requires security if, as a result of the acquisition, any contractor (and/or any subcontractor) employee:

- (a) Will develop, have the ability to access, use, or host and/or maintain federal information and/or federal information system(s) that may be sensitive, including instances of remote access to or physical removal of such information beyond agency premises or control; or
- (b) Will have regular or prolonged physical access to a “federally-controlled facility,” as defined in *FAR Subpart 2.1*.

All covered procurements require compliance with numerous Executive Directives and Orders; Federal Regulations, Directives and Polices; Office of Management and Budget Policies and Memoranda; National Institute of Standards and Technology Guidance; *HHS Policies and Guidance*; and, *FDA-specific Policies and Guidance*. *That being stated, the HHS Security and Privacy Language for Information and Information Technology Acquisitions Guide (HHS SPLI2TA Guide), to be released circa March 2017*, as supplemented by FDA-specific Policies and Guidance Materials, shall serve as the primary resources for FDA acquisition workforce personnel.

**Note:** Use of the **HHS SPLI2TA Guide** Checklist (**Appendix A**) is mandatory when the acquisition requires contractor personnel to develop or access federal information systems. Use of the *Prospective Offeror Non-Disclosure Agreement Template* (**Appendix B**) and *Contractor Non-Disclosure Agreement Template*

(**Appendix C**) are also mandatory, when applicable, in accordance with the *HHS SPL/2TA Guide*. A copy of all applicable *HHS SL/2TA Guide* Appendices shall be completed and attached hereto.

**9.2. Privacy Office Reviews.**

All performance requirements that involve the creation, collection, use, processing, storage, maintenance, dissemination, disclosure, and/or disposal of information that identifies and is about individuals are subject to Privacy Laws that may include the Privacy Act of 1974, the e-Government Act, the Health Insurance Portability and Accountability Act, and/or others. Such being the case, covered Statements of Work, to include any variations thereof (e.g., Performance Work Statements and Statements of Objectives), must be made available for review by the FDA's Senior Official for Privacy. To ensure completion of necessary reviews prior to RFC submittal to OAGS, the Privacy Office should be contacted at [FDAPrivacyOffice@fda.hhs.gov](mailto:FDAPrivacyOffice@fda.hhs.gov) as early in the acquisition planning process as possible. The Senior Official for Privacy will make a determination whether or not a formal Privacy review is necessary. That determination, along with any review findings – irrespective of the outcome – shall be attached hereto.

When a Privacy review is conducted, it will include assessing the need to establish a “system of records”; and, if required, coordinate actions to ensure appropriate solicitation provisions and contract clauses are included in the solicitation and ensuing award(s). The Senior Official for Privacy may also determine that additional provisions (beyond those regarding a Privacy Act system of records) are necessary in order to meet applicable privacy requirements of OMB, HHS, and FDA policies. In these instances, necessary solicitation provisions and contract clauses may include those concerning limitations on the permissible use of information about individuals; obligations in the event of a breach or misuse of information; and, responsibilities for returning or destroying information at the end of the contract. See *OMB Circular A-108, Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act*, reissued December 23, 2016, for more information.

**9.3. Precision Medicine Initiative (PMI) Privacy and Security Plans.**

Until recently, most medical treatments were designed for the average patient. The Precision Medicine Initiative (PMI) is an emerging field of medicine that takes into account individual differences in people's genes, microbiomes, environments, and

lifestyles -- making possible more effective, targeted treatments for diseases like cancer and diabetes.

On October 21, 2016, the Office of Management and Budget (OMB) released *Memorandum 17-02, Precision Medicine Initiative Privacy and Security*, requesting that agencies involved in PMI activities ensure adequate privacy and security protections for such actions. Agencies (to include HHS) were charged to incorporate the PMI Privacy and Trust Principles, as well as PMI Security Framework (both delineated in the subject OMB Memorandum), into covered extramural and intramural activities.

**Note:** Covered solicitations shall include a separate technical evaluation factor specifically addressing the Offeror's PMI Privacy and Security Plan. The Plan shall specify how the entity will incorporate the PMI Privacy and Trust Principles, as well as PMI Security Framework, into its PMI program support activities. The Plan shall describe the processes and procedures that will be followed to ensure appropriate privacy safeguards for IT Systems and PMI Data at stages relevant to applicable work and performance requirements. The awardee's PMI Plan shall then be incorporated by reference into any resultant award to give it full force and effect.

**10. Information Technology (IT) – FDA/HHS CIO Review of Strategies and Plans.**

*Office of Management and Budget (OMB) Circular A-130* provides guidance to Federal agencies on general policy for the planning, budgeting, governance, acquisition, and management of Federal information, personnel, equipment, funds, information technology (IT) resources and supporting infrastructure and services. Agencies must have information security programs that consider the risks and range of threats to information assets and implement controls to mitigate those risks to acceptable levels.

All Acquisition Strategies and Acquisition Plans (as described in *FAR Part 7*) and Interagency Agreements (such as those used to support purchases through another agency) that include IT goods and/or services must be reviewed and approved by the FDA Chief Information Officer (FDA CIO) or his/her Designee. The FDA CIO or Designee will consider the following factors when reviewing Acquisition Strategies and Acquisition Plans:

- (a) Alignment with mission and program objectives in coordination with program leadership

- (b) Appropriateness with respect to the mission and business objectives supported by the IT strategic plan
- (c) Appropriateness of contract type for IT-related resources
- (d) Appropriateness of IT-related portions of statement of needs or Statement of Work
- (e) Ability to deliver functionality in short increments
- (f) Opportunities to migrate from end-of-life software and systems, and to retire those systems.

See OMB Circular A-130, Managing Federal Information as a Strategic Resource, revised July 27, 2016.

**Note:** The HHS Acquisition Strategy Template has a signature block pre-filled for the FDA CIO; the HHS Acquisition Plan Template does not. Any RFC with an IT goods or services component shall include the FDA CIO in the iProcurement approval chain for review prior to submittal to OAGS for processing. OAGS will not process any covered SRFCs that do not demonstrate prior FDA CIO approval on the Requisition document funding the corresponding action. See the *Federal Information Technology Acquisition Reform Act (FITARA) Summary Approval Guidelines* provided herein as **Attachment 2**.

**Note also:** Covered Acquisition Strategies and Acquisition Plans meeting certain threshold dollar values also require HHS-level approvals. See id.

**11. Research Involving Human Subjects.**

Prior to award of a contract for research involving human subjects, prospective contractors must provide assurance that the activity will undergo initial and continuing review by an appropriate Institutional Review Board (IRB). See applicable HHS Regulations provided at *45 CFR 46.103*.

The Contracting Officer will require a Federal-Wide Assurance (FWA) approved by the HHS Office for Human Research Protections (OHRP) from each contractor, subcontractor, or institution engaged in human subjects research. OHRP administers the assurance covering all HHS-supported or HHS-conducted activities involving human subjects. See *HHSAR Subpart 370.3*.

**12. Organizational and Consultant Conflicts of Interest (COI).**

Whenever a specific procurement raises concerns regarding any actual, potential, or apparent COI, such matters need be fully analyzed and addressed prior to solicitation release and/or contract award. Timely disclosure of any and all relevant COI information to the OAGS Contracting Officer/Contract Specialist is mandatory. See *FAR Subpart 9.5* for an in depth discussion of common scenarios and necessary safeguards.

**13. Project Labor Agreements (PLAs) – Construction.**

Applicable to all construction projects with a total estimated cost greater than or equal to \$25 Million. Contracting Officers are required to prepare a PLA Decision Memorandum to the contract file – to be jointly signed by the Program/Project Manager – that documents whether or not a PLA will be used for a covered contract prior to issuing an underlying solicitation. See *FAR Subpart 22.5* and *HHS Acquisition Policy Memorandum 2011-3, Project Labor Agreements, dated July 25, 2011*.

**14. Promotional Items.**

The FDA shall not use appropriated funds (whether from an annual appropriation, multi-year appropriation, appropriated user fee, mandatory appropriation, gift funds, or reimbursements from such appropriations, etc.) to purchase promotional items when they are not a necessary expense. Any such expenditure requires a written justification to be included in the contract file. The justification must explain why the purchase is a necessary to directly further the FDA mission, as well as address how the costs have or will be determined to be reasonable. See *HHS Policy on Promoting Efficient Spending - 3. Use of Appropriated Funds for Promotional Items, issued January 3, 2012*.

**15. Printing and Publications.**

The FDA shall limit the publication and printing of hard copy documents for internal and external use. In addition, FDA personnel shall use sustainable practices to meet their needs (e.g., double-sided printing, black and white printing vs. color, use of 'draft' quality rather than 'high' quality printing). The FDA shall also leverage pre-existing strategic sourcing vehicles (e.g., OMB's Federal Strategic Sourcing Initiative (FSSI) (<http://www.gsa.gov/portal/content/111983>) and the NIH Government Wide Acquisition Contract for Electronic Computer Store III (ECS III)) to procure necessary print management services to

the greatest extent practicable. If none of those vehicles meet the FDA's needs for print management services, a justification shall be completed and placed in the contract file prior to issuing any respective award. See *HHS Policy on Promoting Efficient Spending - 4. Use of Appropriated Funds for Printing and Publications, issued January 3, 2012*.

**16. Public Access to Results of FDA-Funded Scientific Research.**

When public access to results of FDA-funded scientific research may be required, specific language must be incorporated into covered solicitations and awards. See *FDA Staff Manual Guide 2126.4* and *FDA's Plan to Increase Access to Results of FDA-Funded Scientific Research, dated February 2015*.

**Note:** Covered procurements require FDA review and approval of contractor-provided Data Management Plans. It is highly encouraged that the Data Management Plans be leveraged as an evaluation factor or discriminator for award.

**17. Rights in Data, Patents, Copyrights, and Royalties.**

Whenever a specific procurement raises concerns regarding rights in data, patents, copyrights, or royalties, such matters need be fully analyzed and addressed prior to solicitation release and/or contract award. Timely disclosure of any and all relevant information to the OAGS Contracting Officer/Contract Specialist is mandatory. HHS, Office of General Counsel review and approval may be required, subject to the discretion of the Contracting Officer. See *FAR Part 27* for general guidance and further information.

**18. Sustainable Acquisition – Environmental Factors.**

Special requirements apply to those procurements under which green products or services may be supplied or used. Such acquisitions include, but are not limited to: office supplies; construction, renovation or repair; building operations and maintenance; landscaping services; pest management; electronic equipment, including leasing; fleet maintenance; janitorial services; laundry services; cafeteria operations; meetings and conference services. See *HHS APM 2011-05, Sustainable Green Acquisition, dated 10/07/2011*, and *FAR Subpart 23.1* for more information.

**Note:** Covered solicitations shall include a separate technical evaluation factor specifically addressing sustainability requirements, which may serve as a mandatory qualification criterion, as appropriate.

Prior to releasing a covered solicitation, the Contracting Officer/Contract Specialist shall forward the method of evaluation and relative importance of the sustainability criterion to the FDA's Sustainability Official for review and approval.

If after review of the requirement it is determined that there is no opportunity to acquire green products or services, the contract file must be documented and the determination must be noted in the solicitation.

**19. Other Known Clearance(s)/Approval(s).**

Specify the type of other known clearance(s)/approval(s) required (e.g., Service Acquisition Initiative Reviews required by *HHS APM 2011-02, HHS' Prospective Service Acquisition Reviews, dated June 3, 2011*; Appropriations Law Compliance Reviews required by *HHS APM 2011-04, Appropriations Law Compliance Reviews, dated October 6, 2011*).

**COMPLETED BY:**

(Insert Signature)

(Insert Date)

---

(Insert Printed Name of Program Official)  
(Insert Official Title and Center)

Date

**APPROVED BY:**

(Insert Signature)

(Insert Date)

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(Insert Printed Name of P/PM)  
(Insert Official Title and Center)

Date