National Institutes of Health
Office of Management

National Institutes of Health Contracting Officer's Representative (COR) Handbook

Acquisition Planning to Contract Closeout

NIH Optimize Acquisitions

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Version #	Author	Effective Date	Changes Made
1.0	Optimize Acquisitions Program/Contracting Workforce WG	December 2020	Baseline Version

Table of Contents

Contracting Officer Representative (COR) Handbook

Introduction

NIH Optimize Acquisitions

The NIH Optimize Acquisitions program has developed this handbook, with input from Contracting Officers (COs) and Contracting Officer's Representatives (CORs), as a reference guide for the COR to maneuver through the Acquisitions Process. This guide is not intended to supersede COR training but to provide additional reference support.

The Acquisitions Process has been divided into three phases: Planning, Contract Formation, and Contract Administration. Within the three phases, best practices are explained for each of the nine steps of the NIH negotiated Acquisitions Process. The roles and responsibilities of the CO, CS, COR and other relevant individuals are explained. Each step also includes examples of procedures, associated documents, references to the Federal Acquisition Regulations (FAR) where applicable, and expected outcomes.

Planning Phase			Contract Formation Phase				Contract Administration Phase	
Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9
Initial Acquisition Planning Meeting	Market Research & Acquisition Strategy	Acquisition Plan	Solicitation	Evaluation & Negotiation	Source Selection	Award	Administration	Closeout

Each step is structured as follows:

- (1.0) Introduction: Provides an overview of the step.
- (2.0) Purpose: Provides the reason for the step.
- (3.0) Roles and Responsibilities: Defines the key personnel involved and their duties in the step.
- (4.0) Expected Outcome: Defines the results to be achieved at the completion of the step.
- (5.0) Associated Documents: Provides a list of documents which may require input from the COR. Also includes templates and samples which the COR may reference to assist in developing documents required in each step.

For more information, refer to the National Institutes of Health Office of Acquisition Management and Policy's Electronic Guide to NIH Acquisition.

Step 1: Initial Acquisition Planning Meeting

NIH Optimize Acquisitions

1.0 Introduction

The purpose of this document is to outline the steps for an Initial Acquisition Planning Meeting to begin the Acquisitions Process for the Offices of Acquisitions at the National Institutes of Health.

2.0 Purpose

The purpose of an Initial Acquisition Planning Meeting is to discuss the requirements of a new contract and for the Program representative(s) (Project Officer (PO) and/or COR) and Acquisitions representative(s) (CS and/or CO) to work together to formulate the best way to move forward with the acquisition. If the acquisition requires support from other offices, those staff members may be invited to attend the Initial Acquisition Planning Meeting. Invitees may include but are not limited to a Scientific Review Officer (SRO), Information Systems Security Officer (ISSO), Chief Information Officer (CIO), Subject Matter Experts (SMEs), Section 508 Coordinator, Privacy Coordinator, etc.

The necessary lead time that will be required will vary depending on the details of each particular acquisition. The Office of Acquisitions (OA), in concert with the Program representative(s), will establish an appropriate time frame and set target milestone dates for each step of the process. In some Institutes/Centers, schedules are developed in coordination with another office, such as an Office of Initiative Development.

3.0 Roles and Responsibilities

Contracting Officer's Representative (COR): The COR initiates communication with their servicing OA to notify them of a requirement. At the Initial Acquisition Planning Meeting, the COR will provide a general overview of the requirement, discuss significant factors impacting the schedule for establishing a target date for award, and provide additional background information for the requirement.

Contracting Officer (CO) / Contract Specialist (CS): The CO/CS will serve as an acquisition liaison and will provide business advice and guidance to the COR. The CO/CS will establish a milestone schedule of steps in the Acquisition Process to receive the desired supplies or services by an established target date.

4.0 Expected Outcome

Agreed upon course of action for the proposed acquisition by CO/CS and COR.

5.0 Associated Documents

Some examples of documents that may be used to guide pre-initiative meetings:

- Pre-Initiative Planning Meeting for Solicited Contract Initiatives Checklist (See Appendix 1A).
- Summary of Acquisition Planning Meeting (See Appendix 1B).

Appendix 1A: Pre-Initiative Planning Meeting for Solicited Contract Initiatives Checklist (R&D)

Pre-Initiative Planning Meeting (PIPM)
for
Solicited Contract Research Initiatives

Background Issues, Questions and Considerations

Background

Pre-initiative Planning Meetings (PIPM) are designed to assemble the key Acquisition Team Members involved in the planning, preparation, quality control, peer review and award of the solicited Research and Development (R&D) contract initiatives to discuss a fairly broad range of scientific, technical, policy and financial aspects for each approved initiative prior to the development of the first draft RFP. The list of issues, questions and considerations provided in this document forms the basis for PIPM and, therefore, both Office of Acquisition (OA) and Program Division staff are expected to come to the meetings prepared to discuss all issues, questions and considerations that are appropriate for the specific initiative being addressed.

Pre-Initiative Planning Meeting may include but not limited to:

Representatives from the Program Divisions:

- COR
- Branch Chief
- Program Officer
- Division Coordinator(s)

Representatives from the OA and other support offices:

- Contracting Officer and Contract Specialist
- OA Policy Analyst
- Scientific Review Officer (SRO)
- Scientific Review Program (SRP) Branch Chief
- Information Systems Security Officer (ISSO)
- If intellectual property rights issues are involved, a representative from the appropriate Office of Technology Development

Timing for PIPM: The Contract Specialist/Contracting Officer is responsible for scheduling PIPM meetings. The meetings are scheduled no later than 4-6 months prior to the due date for the posting of the RFP.

Issues, Questions and Considerations

1. **What do you want to accomplish with this initiative?**

    a. What are the major objectives?

    b. Are the scientific areas adequately related to ensure a cohesive focus and to avoid lumping different areas of research within a single solicitation?

    c. Is the scope of the defined research realistic and feasible in terms of the current knowledge base and available technologies, facilities, trained personnel, etc.

2. **Who will submit proposals?**

    a. Is there an adequate pool of qualified investigators who are capable of performing the defined research and who will be interested in responding? Can you identify 10-12 such investigators?

    b. How many proposals do you anticipate receiving?

    c. Do you wish to allow foreign institutions to respond? If so, why? Is there a need to exclude foreign institutions? If so, why?

3. **How realistic is the funding for this initiative?**

    a. Has the funding for this initiative changed significantly? If so, what changes in research scope will be made to accommodate the funds approved?

    b. Can the research be performed for the available funds based on cost estimates from related research?

    c. Is there a need for a dollar cap on individual budget requests?

    d. For contract recompetitions, what has been the spending rate, what is the balance of funds available, and will the unexpended balance be sufficient for the contractor to complete the project by the end date?

4. **How realistic is the phasing plan?**

    a. Is there adequate time for offerors to prepare quality proposals? Factors to consider include:

        - Complexity of the research being solicited
        - Special proposal requirements, e.g., well developed proposed clinical protocols, prototypes, matching funds, host country clearances, etc.
        - Time required to arrange appropriate multi-disciplinary collaborations with other institutions/organizations in the U.S. and in foreign countries
        - Information technology clearances from IT staff
        - Intellectual property rights review by the appropriate Office of Technology Development

    b. If a transition period is necessary, should the incumbent contractor not be successful, has sufficient time been built into the phasing plan to allow for this?

5. **For contract recompetitions, what improvements can or should be made?**

    a. Did the previous solicitation receive as many responses as anticipated and/or as necessary to carry out the research? If not, why?

    b. What feedback, if any, did peer reviewers provide about the previous solicitation?

    c. Were the review/technical evaluation criteria appropriate and adequate for assessing technical merit and capability?

    d. Were the cost estimates for the contract realistic and did they hold up over the course of the project period?

    e. Did offerors have sufficient time and space (page limits) to prepare proposals capable of addressing the scope and requirements of the solicitation?

    f. Were RFP and/or amendments, submission deadline extensions required? If so, why?

    g. Did the products/outcomes of the previous research effort meet expectations? If not, are there aspects of the solicitation that should be modified to improve the overall outcomes?

    h. What changed in the contract through modification from the award until the determination for the recompetition?"

6. **What is the proposed method of solicitation?**

    a. For contract solicitations, what aspects of the research require an acquisition approach? What types of services are being considered?

    b. Is this initiative modeled after a known contract? If so, which one and why?

    c. Were other funding methods considered, e.g., Interagency Agreement with another DHHS component or another agency?

7. **How will the research scope and requirements be defined?**

    a. What type of background information is necessary to ensure that potential offerors understand the history and context of the research? For example, if collaboration or coordination with existing research programs is anticipated, what information about those existing research programs is needed? If there is an incumbent contractor, information about this should be included along with a description of the functions being performed and a requirement to plan for an orderly transition to a potential new contractor.

    b. What special proposal requirements do you anticipate including and why? How will the information required assist in assessing scientific merit and feasibility?

    c. Will there be a need for any special terms or conditions of award? Incentives? If so, what would they cover and why?

    d. What page limitations are appropriate for the various sections of the proposal?

8. **Please address the following questions:**

    a. Are there at least two small businesses capable of performing the required work? If so, the government is required to set-aside the contract for small businesses, meaning that only small businesses are eligible to submit a proposal. In the health research industry, small businesses are usually defined as organizations with less than 500 employees, although other factors such as annual revenue ceilings may be taken into consideration.

    b. Are any special technical proposal instructions necessary and what uniform assumptions for the business proposal need to be incorporated into the solicitation?

    c. Is there a need to allow for options under the solicitation? For example, expansion of the type and/or quantity of services to be provided in future years should the government choose to exercise an option. If options will be included, the Independent Government Cost Estimate (IGCE) must include the estimated costs for all options and the funds required to exercise options must be available within the approved set-aside for the initiative.

    d. Will any government furnished property (GFP) be required? For recompetitions, is there GFP under the incumbent contract that can be transferred to a new contractor? If so, is it outdated?

9. **Will there be special peer review needs?**

    a. Are the standard NIH review criteria for contract initiatives adequate? If not, what additional review criteria do you anticipate incorporating into the solicitation and why?

    b. Are you considering changes to the normal peer review process such as multiple review groups, site visits, audits prior to award or other modifications?

10. **Will collaboration/coordination with other research programs be required/beneficial?**

    a. within your Division
    b. within your IC
    c. with other NIH Institutes and Centers
    d. with other DHHS and Federal agencies

Appendix 1B: Summary of Acquisition Planning Meeting (Non-R&D)
This form is not mandatory but may be used as a useful tool.

Summary of Acquisition Planning Meeting

Project Title: _____

Project Description: _____

Contracting Officer's Representative: _____

Contracting Officer / Contract Specialist: _____

Anticipated Award Date: Award to start on or before _____

Acquisition Vehicle:
Examples of acquisition vehicles that can support an acquisition include (but not limited to):

- GSA Federal Supply Schedule
- NITAAC CIO-SP3
- Public Information and Communication Services (PICS II)
- Full & Open Competition
- Governmentwide Acquisition Contracts (GWACs)
- SBA 8(a) Program

Acquisition Vehicle Comments:
•

Acquisition Approach:
Examples of acquisition approaches that can support an acquisition include (but not limited to):

- Single Solicitation / Single Award
- Single Solicitation / Multiple Awards
- Multiple Solicitations / Multiple Awards

Acquisition Approach Comments
•

Contract Types:
Examples of acquisition contract types that can support an acquisition include (but not limited to):

- Fixed-Price
- Time & Materials
- Cost-Reimbursement
- IDIQ

Contract Types Comments
•

High-Level Estimated Timeline/Milestone:

The target award date: _____

Per our discussion, below is an estimated timeline for this acquisition:

Milestones (if applicable)	Estimated Duration (calendar days)
Acquisition Strategy	
Market Research/Synopsis	
Acquisition Plan Routed/Approved*	
Small Business Review (HHS-653)	
Pre-Solicitation Notice	
RFQ/RFP Released	
Quotations/Proposals Received	
Review/Evaluations Completed	
Negotiations/Final Proposal Revisions	
Source Selection	
Target Award Date	

** Dates for AP routing and approval may be longer depending on who and how many individuals may be included and their respective availability.*

Step 2: Market Research & Acquisition Strategy

NIH Optimize Acquisitions

1.0 Introduction

The purpose of this document is to outline the steps for conducting Market Research and developing the Acquisition Strategy for the Offices of Acquisitions at the National Institutes of Health.

Per the Department of Health and Human Services (HHS) Directive for Acquisition Strategy (referenced in Associated Documents, below), HHS requires that all programs/projects (P/P) augmented by contractor services/support must fall within an Acquisition Strategy (AS) that discusses the conceptual basis of the overall mission and business need. The AS is a high-level description. An AS relates to the overall mission of a program not a specific contract. A single AS may support multiple Acquisition Plans for separate but related acquisitions. Therefore, identification of an appropriate, existing AS or development of a new AS must occur before preparation of the Acquisition Plan.

Market Research must also be conducted prior to completing an Acquisition Plan. The results of Market Research will be discussed within the Acquisition Plan. Results of Market Research are also a key component in considering whether an acquisition should be set-aside for small businesses, another item discussed in the Acquisition Plan.

2.0 Purpose

In general, a primary goal in developing an AS is to minimize the time and cost of satisfying an identified, validated need consistent with common sense, sound business practices, and basic policies. An AS is required when a mission need is defined, and the P/P will be augmented by contractor support. The AS is prepared prior to milestones and addresses the critical elements of the P/P to include: management approach; business strategy; risks; technology; resources; requirements roadmap; procurement forecasting; testing; training; implementation phases; and other logistics support over the entire P/P life cycle. The strategy evolves through an iterative process and becomes more definitive in describing the relationship of the essential elements of a P/P. Each AS must be updated whenever there is a change to the approved strategy or as the approach and P/P elements are better designed.

The HHS Directive for Acquisition Strategy, referenced in Associated Documents, below, provides an abundance of guidance on how to develop an AS, along with a Template to be used. HHS Acquisition Policy, Guidance and Instructions (PGI) Subpart 307.1 – Acquisition Planning also includes a discussion of how the AS and AP should be utilized. See Associated Documents for HHS Acquisition Alerts describing when an AS needs to proceed to certain levels of review and approval.

Market research is conducted to identify the Government's minimum requirements for an acquisition; further develop the Government's desired specifications, if necessary; determine whether commercial or non-developmental items could be utilized; identify qualified contractors (including a determination about whether an acquisition should be set-aside for small business); and inform other terms of the anticipated solicitation. See 'Market Research Document' in Associated Documents for a checklist that can be used to guide market research efforts.

A Sources Sought Notice is a type of market research that is often used to describe an upcoming acquisition and request submission of capability statements to help the Government determine whether there are two or more small businesses who would be likely to compete for the associated contract. (An example of a Sources Sought Notice is provided in "Step 3" (Acquisition Plan) of this COR Handbook.) It is the policy of the Government to provide maximum practicable

opportunities in its acquisitions for small business, and it is also the policy of the Government to generally promote competition for contracting opportunities. Therefore, the CO/CS and COR must work together to prepare documentation, for review by NIH and HHS Small Business Specialists, that discusses why or why not the acquisition presents an opportunity for the Government to meet its requirements and also achieve both of those policy objectives. (An example of this small business review, referred to at HHS as the "Office of Small and Disadvantaged Business Utilization HHS 653 – Small Business Review Form," is provided in "Step 3" of this COR Handbook.)

A Request for Information (RFI) is a market research tool that may be used to allow the Government to seek input from industry (and/or academic institutions) to help define its requirement, survey the marketplace to determine what technologies or approaches exist, assess feasibility of a requirement, ask for information about practices/terms/conditions, or ask for any other type of advice that the Government thinks would be useful prior to taking the next steps in an acquisition process.

Another tool that can be utilized is a Draft Request for Proposal (Draft RFP). If the Government has enough information to put together a solicitation, but would find it valuable to receive input about how the solicitation is viewed by the potential offeror community in order to consider changes, a Draft RFP may be a useful approach.

While many market research activities are conducted via public notices posted on the beta.SAM.gov website and in the NIH Guide to Grants and Contracts (https://grants.nih.gov/funding/searchguide/index.html#/), other opportunities for engagement with industry (and/or academic institutions) are generally encouraged by the Federal Acquisition Regulation, as referenced in FAR Part 10 and FAR Subpart 15.201. CORs should communicate with CO/CS staff to ensure that market research activities do not provide an unfair advantage to any potential offerors.

3.0 Roles and Responsibilities

Contracting Officer's Representative (COR): HHS regulations and policies state that Program officials are responsible for AS development. However, close collaboration with and guidance from the CO/CS is a best practice, as review and approval of the AS takes place through agency contracting offices.

The COR shall conduct market research through discussions with professional networks and review of available websites, literature, etc., and will prepare the description of the requirement to enable further market research efforts that the CO/CS advises should be conducted, such as Sources Sought Notices, Requests for Information (RFIs), Draft Requests for Proposals (Draft RFPs), or other types of exchanges with potential offerors.

Contracting Officer / Contract Specialist (CS): The CO/CS will serve as an acquisition liaison in providing business advice and guidance to support the development of the AS, as discussed above.

The CO/CS shall determine whether the acquisition would benefit from use of an RFI or Draft RFP, or other type of industry (and/or academic institutions) exchanges, and work in collaboration with the COR to implement these market research efforts.

Office of Acquisition Policy: If the OA has a Policy Office or Procurement Analyst, this role will often be engaged to review and provide any recommendations to strengthen the AS, particularly prior to its routing for review and approval by the NIH and/or HHS.

4.0 Expected Outcome

Approved AS and market research which provides a basis for more detailed planning.

5.0 Associated Documents

- HHS Directive for Acquisition Strategy (Revised 9/2017)
- Acquisition Strategy (See Appendix 2A)
- Acquisition Alert 2019-01 (See Appendix 2B)
- Acquisition Alert 2018-03 (See Appendix 2C)

Appendix 2A: Acquisition Strategy

To access the Acquisition Strategy, please click on the PDF located below:

Acquisition
Strategy Template.p

Appendix 2B: Acquisition Alert (2019-01)

ACQUISITION ALERT 2019-01

HHS Acquisition Review

TO: Heads of Contracting Activity

FROM: Andrea Brandon //s//
Deputy Assistant Secretary for Grants and Acquisition Policy
And Accountability and Senior Procurement Executive

SUBJECT: HHS Acquisition Review Pilot Program

EFFECTIVE DATE: November 29, 2018

Purpose:

The purpose of this memorandum is to extend the HHS Acquisition Review Pilot Program

Applicability:

This guidance and implementation instructions set forth in this memorandum are applicable to all contract actions. All acquisition programs and projects across HHS are eligible to participate in the pilot as established with Acquisition Alert 2018-03.

Roles and Responsibilities:

It is the HCA's responsibility to ensure widest distribution of this notice throughout HHS staff and operating divisions and to update an applicable policies and procedures to reflect this guidance.

Guidance:

The HHS Acquisition Review Pilot Program was established for the period of September 10, 2018 through January 9, 2019 and outlined in acquisition alert 2018-03. In order for both HHS and the OPDIVs of HHS to achieve the best results of the pilot initiative to streamline acquisition reviews, the pilot program will be extended through September 30, 2019.

HHS awards the majority of our contracts during the third and fourth quarter of each fiscal year. This is often necessary due to the federal budget and funding process. The current Acquisition Review Pilot period occurs when not many acquisitions occur. In order to gain a larger sampling of HHS acquisitions and determine if the pilot can become operation and streamline the acquisition reviews while ensuring transparency and accountability the pilot has been extended through September 30, 2019.

NIH Guidance for Implementing the HHS Acquisition Plan/Acquisition Strategy Review Pilot Program

(Acquisition Alert 2018-03, and 2019-01 effective September 10, 2018, through September 30, 2019)

Acquisition Alert 2018-03 implements the HHS Acquisition Review Pilot Program, which increases the review thresholds for Acquisition Plans and Acquisition Strategies during the pilot period, September 10, 2018, through January 9, 2019.[1,2] Acquisition Alert 2019-01 extends the pilot to September 30, 2019. At the conclusion of the pilot period, we return to the old review thresholds. HHS/OAP will evaluate the data from the pilot program to determine if the increased review thresholds become permanent.

ACQUISITION STRATEGIES	
Program/Project Total Lifecycle Cost	**Approval Level**
< $50M	OA Director
≥ $50M - < $100M	Head of the Contracting Activity, NIH
≥ $100M - < $150M	Deputy Director for Management, NIH
≥ $150M	HHS/Office of Acquisition Policy

ACQUISITION PLANS	
Total Dollar Amount	**Approval Level**
SAT Threshold - $20M	One level above the Contracting Officer
> $20M - < $50M	OA Director
≥ $50M - $150M*	Head of the Contracting Activity, NIH
> $150M	HHS/OAP
High Risk Acquisitions Regardless of Dollar Amount[3]	HHS/OAP
Special Interest Acquisitions Regardless of Dollar Amount[4]	HHS/OAP

* Informational copies of APs > $50M but ≤ $150M will be provided to HHS/OAP by DAPE.

11/30/18

File Submission Requirements and Procedures

Files to be considered for review/approval during the pilot program (i.e. to be approved by the NIH HCA or NIH Deputy Director for Management (DDM)) must be submitted to the Division of Acquisition Policy and Evaluation (DAPE) no later than August 19, 2019. This will permit sufficient time for NIH reviews/approvals before the process reverts to the original procedure(s).

All files, including supporting documentation, should be submitted to the DAPE mailbox at dape@od.nih.gov.

Acquisition Strategies submitted for NIH DDM and/or HHS/OAP review/approval shall also include a slide presentation.

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[1] All Acquisition Strategies requiring FITARA review by the Office of the Chief Information Officer (OCIO) are separate and apart from this policy and still applicable.

[2] Other HHS acquisition policies and guidance shall remain in effect throughout the pilot period.

[3] Defined as having one or more risks with a high probability of occurring and significant associated consequences or the program or initiative has been designated as "High Risk" by the U.S. Government Accountability Office (GAO).

[4] A program or project can be designated as "Special Interest" by their OPDIV Leadership or the ASRB if it meets one or more of the following criteria: 1) high technical complexity; 2) Congressional interest; 3) requires a large commitment of resources; 4) the P/P is critical to achievement of a capability or set of capabilities; 5) the P/P is part of a system of systems; 6) the P/P affects more than one Division across HHS; 7) the PIP is led by a P/PM who is not FAC-P/PM certified within one year of appointment as the P/PM; and 8) as designated by the Office of the Secretary.

Appendix 2C: Acquisition Alert (2018-03)

ACQUISITION ALERT 2018-03

HHS Acquisition Review

TO: Heads of Contracting Activity

FROM: Andrea Brandon
Deputy Assistant Secretary for Grants and Acquisition Policy
And Accountability and Senior Procurement Executive

SUBJECT: HHS Acquisition Review Pilot Program

EFFECTIVE DATE: September 10, 2018 through January 9, 2019 (120 days)

Purpose:

The purpose of this memorandum is to implement an HHS Acquisition Review Pilot Program

Applicability:

This guidance and implementation instructions set forth in this memorandum are applicable to all contract actions. All acquisition programs and projects across HHS are eligible to participate in this pilot.

Roles and Responsibilities:

It is the HCA's responsibility to ensure widest distribution of this notice throughout HHS staff and operating divisions and to update an applicable policies and procedures to reflect this guidance.

Guidance:

During the HHS Acquisition Review Pilot the following special rules shall be in effect:

- Acquisition Strategies (AS) must be reviewed by the Department/Office of Acquisition Policy (OAP) for all programs or projects with a total lifecycle cost equal to or greater than $150 million. All AS below this threshold shall be reviewed and approved by the Operating and Staff Divisions (OPDIV and STAFFDIV). The HCA is responsible for drafting guidance for approval of ASs developed for acquisition strategies with an estimated value equal to or less than $150 million.

- Each Head of Contracting Activity (HCA) shall provide the OAP with written notification of all acquisitions with a total value greater than $50 million but equal to or less than $150 Million. OAP will review notifications provided and request additional information, if necessary. Notification shall be provided to OAP by submitting a copy of the contract acquisition plan with a notation of "for informational purposes only". Documents shall be submitted to SI@hhs.gov

- Acquisition Plans (AP) shall be reviewed and approved at the following levels:
  - Simplified Acquisition Threshold (SAT) to $20 million – One level above the Contracting Officer (CO)
  - Greater than (>) $20 million to $100 million – HCA or designee
  - Greater than (>) $100 million to $150 million – Chief Operating Officer or designee
  - Greater than $150 million – Department/OAP
  - Any value and designated as "High Risk" – Department/OAP
  - Any value and designated as "Special Interest" – Department/OAP
- OAP shall review the APs for all contracts regardless of their dollar value for programs or projects:
  - Designated as "High Risk" – A program or project can be designated as "High Risk" by the OPDIV Leadership or the HHS Acquisition Strategy Review Board (ASRB) if it meets one or more of the following criteria: 1) has one or more risks with a high probability of occurring and significant associated consequences; and, 2) the program or initiative has been designated as "High Risk" by the U.S. Government Accountability Office (GAO).
  - Designated as "Special Interest" – A program or project can be designated as "Special Interest" by their OPDIV Leadership or the ASRB if it meets one or more of the following criteria: 1) high technical complexity; 2) Congressional interest; 3) requires a large commitment of resources; 4) the P/P is critical to achievement of a capability or set of capabilities; 5) the P/P is part of a system of systems; 6) the P/P affects more than one Division across HHS; and, 7) the P/P is led by a P/PM who is not FAC-P/PM certified within one year of appointment as the P/PM, 8) as designated by the Office of the Secretary
- All APs requiring review by the Office of the Chief Information Officer (OCIO) are separate and apart from this policy and still applicable.
- Other HHS acquisition policies and guidance shall remain in effect throughout the pilot period.

Step 3: Acquisition Plan

NIH Optimize Acquisitions

1.0 Introduction

The purpose of this document is to outline the steps for development of the Acquisition Plan (AP) for the Offices of Acquisitions at the National Institutes of Health. The Federal Acquisition Regulation (FAR) requires agencies to perform acquisition planning for all acquisitions in order to promote:

- The acquisition of commercial items or, to the extent that commercial items suitable to meet the agency's needs are not available, non-developmental items.
- Full and open competition per FAR Part 6 or, when full and open competition is not required in accordance with Part 6, to obtain competition to the maximum extent practicable.

2.0 Purpose

In general, the purpose of the AP is to ensure that the Government meets its acquisition needs of goods (supplies) and services in the most effective, economical, and timely manner.

3.0 Roles and Responsibilities

Contracting Officer's Representative (COR): HHS regulation and policy state that program officials are responsible for developing the AP. However, close collaboration with and guidance from the CO/CS is a best practice, as review and approval of the AP takes place through agency contracting offices. Generally, a COR should attempt to fill out the AP template to the extent that he/she is able, and then work with the CO/CS to complete the sections that are unfamiliar.

Additionally, there are various other documents created during the acquisition planning process, examples of which are listed below in the table in Section 5.0, Associated Documents. The column (Person(s) Responsible) indicates whether each document is generally a primary responsibility of the COR or of the CO/CS.

Contracting Officer (CO) / Contract Specialist (CS): The CO/CS will serve as an acquisition liaison in providing business advice and guidance to support the development of the AP, using the template established by HHS. Additionally, there are various other documents created during the acquisition planning process, beyond the AP template itself, that are listed in the table below in Section 5.0 Associated Documents. The column (Person(s) Responsible) indicates with whom the primary responsibility rests.

Institute-Center/Program: COR Supervisor, Budget Officer, Information Security Systems Officer (ISSO), Executive Officer (EO) and IC Director review the AP (as applicable).

NIH/HHS: NIH Policy Office and Head of Contracting Activity (HCA), Office of Grants and Acquisition Policy and Accountability (HHS policy Office) and the Small Business Office (SBO) review the AP (as applicable).

4.0 Expected Outcome

An AP must be approved at the level required by regulation and policy before a solicitation may be released requesting proposals or quotes. HHS and NIH have established approval levels that are set forth in ***Acquisition Alert 2019-01*** (Appendix 3R within the Associated Documents, below). The individual Office of Acquisitions (OA) handling the acquisition may have additional requirements for acquisitions below the dollar levels addressed in that document.

5.0 Associated Documents

- HHS AP Directive: Federal Acquisition Regulation 7.105 specifies the content requirements for a written Acquisition Plan (AP)

Note: the forms included here are provided as examples. Please consult your specific Office of Acquisitions for specific forms and procedures.

Appendix	Title	Person (s) Responsible
Appendix 3A:	Acquisition Plan Template	COR and CO
Appendix 3B:	Statement of Work (Attachment 1)	COR
Appendix 3C:	Technical Evaluation Criteria/Mandatory Criteria (Attachment 2)	COR
Appendix 3D:	Reporting Requirements and Deliverables (Attachment 3)	COR
Appendix 3E:	Additional Technical Proposal Instructions & Additional Business Proposal Instructions (Attachment 4)	COR
Appendix 3F:	Advance Understandings (as needed) (Attachment 5)	COR
Appendix 3G:	Potential Source List (Attachment 6)	COR
Appendix 3H:	Sources Sought Notice (Attachment 7)	CS
Appendix 3I:	List of Potential Technical Review Members (Attachment 8)	COR
Appendix 3J:	List of Government-furnished property (Attachment 9)	COR
Appendix 3K:	Justification and Approval (J&A) (Attachment 10)	COR
Appendix 3L:	COR Certification (Attachment 11)	COR
Appendix 3M:	Independent Government Cost Estimate (IGCE) (Attachment 12)	COR
Appendix 3N:	Office of Small and Disadvantaged Business Utilization HHS 653 – Small Business Review Form (Attachment 13)	CS
Appendix 3O:	Clearance/R&D Project Concept/Approval Documentation (Attachment 14)	COR and CS
Appendix 3P:	Contract Opportunities Draft Presolicitation Notices (Attachment 15)	CS
Appendix 3Q:	FISMA Certification - Information Security Program Requirements (Attachment 16)	COR
Appendix 3R:	Acquisition Alert (2019-01)	Reference ONLY
Appendix 3S:	Evaluation Factors - Adjectival Ratings and Risk Definitions	Reference for Appendix 3C
Appendix 3T:	Evaluation Factors – Numerical Scores Definitions	Reference for Appendix 3C

Back to Appendix list

Appendix 3A: Acquisition Plan Template

https://intranet.hhs.gov/manual/directive-acquisition-planning

Back to Appendix list

Appendix 3B: Statement of Work (Attachment 1)

STATEMENT OF WORK

PROJECT TITLE
RFP/RFQ NUMBER

1) BACKGROUND and INTRODUCTION:

- Briefly describe, in the form of a paragraph, the overall project and objective(s) in broad terms that indicate the size and magnitude of the effort.
- When appropriate, include the scope of disease, therapeutic/preventive candidate(s), type of research activity, study populations, product development activities, etc.
- Where appropriate, include definitions (i.e.," For purposes of this contract, a candidate vaccine is defined to be …").
- If applicable, list the programs (i.e. existing databases/computer systems, clinical study groups) and/or contractors (i.e. clinical research support services contractors) with which the Contractor will be required to collaborate. More detailed specifications of the relationships will be delineated within the Technical Requirements. Additional RFP/RFQ specific material (which will become separate Attachments to the RFP/RFQ) may be necessary to provide offerors enough background information on these existing programs and/or contracts.
- If applicable, identify research/service activities that are not within the scope of work, i.e. "NOTE: This contract will not provide funds to support Phase 1 clinical trials."
- If Option(s) are planned, describe the scope of work to be performed upon the Government's exercise of the Option(s).

For Re-competitions:

- Provide the project history and contractual history of the acquisition.
- Identify the previous contract number(s) and incumbent contractor(s).
- Describe studies, activities, accomplishments of incumbent contractor(s) in the context of justification for the need of the acquisition and documentation of previous success.
- Identify any changes to the requirement from the previous competition.

2) SCOPE:

- Briefly describe, in the form of a paragraph, the overall project and objective(s) in broad terms that indicate the size and magnitude of the effort.
- When appropriate, include the scope of disease, therapeutic/preventive candidate(s), type of research activity, study populations, product development activities, etc.
- Where appropriate, include definitions (i.e.," For purposes of this contract, a candidate vaccine is defined to be …").
- If applicable, list the programs (i.e. existing databases/computer systems, clinical study groups) and/or contractors (i.e. clinical research support services contractors) with which the Contractor will be required to collaborate. More detailed specifications of the relationships will be delineated within the Technical Requirements. Additional RFP/RFQ specific material (which will become separate Attachments to the RFP/RFQ) may be necessary to provide offerors enough background information on these existing programs and/or contracts.
- If applicable, identify research/service activities that are not within the scope of work, i.e. "NOTE: This contract will not provide funds to support Phase 1 clinical trials."
- If Option(s) are planned, describe the scope of work to be performed upon the Government's exercise of the Option(s).

Helpful Tip: Consider including additional labor options in commercial services contracts with labor categories to allow for additional level of effort and a flexible contract ceiling.

3) TECHNICAL REQUIREMENTS:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below. Specifically, the Contractor shall:

- Describe comprehensively and clearly the work that shall be required of the Contractor including any deliverable or reporting requirement resulting from completion of each particular task or activity.
- Include as appropriate, the responsibilities of the Government, i.e. "The Contracting Officer's Representative (COR) will review the draft protocol and provide comments to the Contractor within 15 calendar days of receipt of the draft protocol."
- Define timelines for the Contractor and the Government in terms of either calendar days or business days and use consistently throughout the Statement of Work and in the Reporting Requirements and Deliverables section.
- Use outline format so that each item, whether a major task/category of functions or a sub-function, has a number or letter identifier to allow reference to all items in the SOW.
- Do not include instructions to offerors on what to include in the Technical Proposal; this information belongs in the "Additional Technical Proposal Instructions" section.

A) Project Management (edit as appropriate)

1. Overall Project Management

a. Provide for the overall management, integration and coordination of all contract activities, including the management and coordination of activities carried out under subcontracts.

b. Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation and timely completion of all projects carried out under this contract and effective communications with the COR and the Contracting Officer (CO).

c. Provide for a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors.

2. Subcontract Management and Reporting (for solicitations anticipating a significant amount of subcontracting)

a. Solicit, evaluate, award and manage subcontracts, including overseeing the technical, administrative and operational activities of subcontractors; audit subcontractor facilities, services, and financial expenditures; and track deliverables and reporting requirements.

b. Assess and provide Quarterly Technical Reports on subcontractor performance and progress toward achievement of defined tasks and responsibilities within established timelines; and identify and resolve problems with subcontractor performance.

c. Ensure that subcontractor personnel, equipment and facilities are compliant with regulatory requirements in effect throughout the contract period of performance.

d. Ensure the complete and effective transfer of technology by the subcontractors to the Contractor, the Government, or a third party designated by the COR.

e. Perform all necessary transition and closeout functions on each subcontract.

3. Meetings and Teleconferences

a. Contract Initiation Meeting

Within 60 calendar days after the effective date of the contract, participate in a one-day Contract Initiation Meeting with the COR, the CO and other NICHD personnel designated by the COR, to be held at the Contractor's site. The purpose of the Contract Initiation Meeting shall be to orient the Contractor to NICHD contract procedures.

b. Monthly Meetings/Teleconferences

1) Plan and conduct meetings at a minimum of monthly intervals, either in person or via teleconference, with the Contractor's key personnel to review overall progress.

2) Plan and conduct meetings of the Contractor's Principal Investigator and Project Manager with the COR and CO at a minimum of monthly intervals, either in person or via teleconference, to review protocols (proposals, etc.), the status of approved projects (protocols, etc.), and to discuss any matters relevant to the scientific and financial administration of the contract and future activities. The schedule for those meetings will be established by the COR and CO after contract award. Prepare and distribute the agenda and meeting/teleconference materials to all participants. Provide a summary of all meetings and teleconferences in the Semi-Annual Progress Reports.

c. Annual Site Visit

Arrange for and conduct annual site visits for contract and program staff to review and discuss: project progress; problems and obstacles and approaches to overcoming identified problems and obstacles; recommendations for modifications in project timelines, objectives, and research approaches/methodologies based on outcomes to date; and future plans. These site visits shall be attended by the Principal Investigator, the Contractor's business representative, and all key personnel. The Contractor shall be responsible for:

1) Planning and submitting the agenda to the COR for approval;
2) Developing written and oral presentation materials;
3) Arranging for the logistics associated with the site visits and for travel costs for all non-Government site visit attendees; and
4) Preparing and submitting Annual Site Visit reports to the COR and CO within 30 calendar days of completion of each annual site visit.

B) Intellectual Property (if not applicable, delete) *Determined based on discussion with COR/CO.*

The Contractor shall be solely responsible for the timely acquisition of all appropriate proprietary rights, including intellectual property rights, and all materials need to perform the project. Before, during, and subsequent to the award, the U.S. Government is not required to obtain for the Contractor any proprietary rights, including intellectual property rights, or any materials needed by the Contractor to perform the project. The Contractor is required to report to the U.S. government all inventions made in the performance of the project, as specified inn FAR 52.227-11 (Bayh-Dole Act).

C) Initial and Final Transition (edit as appropriate)

1. Initial Transition (For renewal solicitations; edit as appropriate)

In the event of transition to a new contractor, ensure an orderly, secure, and efficient transition of activities from the predecessor contractor, as follows;

List those contract activities and contract-generated data and materials that will require transition. Include requirements for the Contractor to develop a Draft Initial Transition Plan for review by the COR, and a Final Initial Transition Plan based on the COR comments. The Draft and Final Initial Transition plan should include not only the activities and contract-generated data and materials to be transferred, but also the timeline for completion of transition activities and the assigned staff. Also specify the timeline for submission of both the Draft and Final Initial Transition Plans and the timeline for completion of the transition.

a. Final Transition or Contract Closeout (if applicable; edit as appropriate)

The Contractor shall ensure an orderly, secure, and efficient transition of contract related materials and activities to the successor contractor or to the Government. A description of transition activities, timelines, and assigned staff shall be provided in a Draft and Final Transition Plan, which will be reviewed and approved by the CO. The Draft Transition Plan shall be submitted _____ months prior to the completion date of the contract, and the Final Transition Plan (approved by the COR and Contracting Officer) shall be submitted ___ months prior to the completion date of the contract.

D) Option(s) (include only for RFPs/RFQs with Options)

In addition to the services/quantities outlined above to be provided for the base requirement, Options(s) for additional services/quantities under the contract may be exercised at the discretion of the Government and are defined as follows:

Contractor requirements for Options that may be exercised by the Government are the last item in the Statement of Work. Number each Option and delineate the scope of work to be performed for each Option. For example:

Option 1: Design and conduct a Phase 3 clinical trial to evaluate further the safety and efficacy of the candidate therapeutic; design and conduct additional preclinical studies for product optimization; provide statistical and data management support for additional Division-sponsored research programs involving clinical studies/trials.

Under each Option, describe the specific tasks/functions to be carried out by the Contractor in sufficient detail to ensure a meaningful and complete specification of requirements. For some Options, this will require a fairly detailed Statement of Work to define Contractor responsibilities.

RFPs/RFQs that include Options must also provide: (1) Technical Proposal Instructions delineating what offerors are to provide in the Technical Proposal; (2) One or more Technical Evaluation Criteria to assess the merit, appropriateness and feasibility of offerors' Technical Proposals with respect to Option(s); and (3) Additional Business Proposal Instructions and Uniform Cost Assumptions for each Option.

Appendix 3C: Technical Evaluation Criteria/Mandatory Criteria (Attachment 2)

ATTACHMENT 2: SECTION M - TECHNICAL EVALUATION FACTORS
PROJECT TITLE
RFP/RFQ NUMBER

MANDATORY QUALIFICATION CRITERIA (if not applicable, delete)

The Mandatory Qualification Criteria establish conditions that must be met ❑ **at the time of receipt of the Original Proposal** ❑ **at the time of receipt of the Final Proposal/Quotation Revision submission** in the Office of Acquisitions, NICHD, in order for your proposal to be considered any further for award. (Note: Submission at the time of Original Proposal receipt is the preferred method for NICHD.)

Listed below are the Mandatory Qualification Criteria. The offeror must include all information that documents and/or supports the Mandatory Qualification Criteria in one clearly marked section at the front of the Technical Proposal. Technical Proposals that are determined by the Project Officer not to meet the Mandatory Qualification Criteria will not be submitted for peer review and will not be considered any further for award.

Mandatory Qualification Criteria:
Insert the criteria here in terms that will allow Program and contract staff to easily determine whether or not the Mandatory Qualification Criteria have been met. Do not include criteria that require a subjective or qualitative assessment. Please note that these criteria will be evaluated by Program and contract staff and NOT by peer reviewers.

Justification for Mandatory Qualification Criteria:
Provide justification for the use of Mandatory Qualification Criteria.

Documentation Required to Support Having Met the Mandatory Qualification Criteria:
Describe the documents or information that offerors must provide to demonstrate that they meet the mandatory qualification criteria.

PRE-AWARD SITE VISIT OR SITE AUDIT (if not applicable, delete; if applicable, edit as appropriate)

Offerors determined, upon completion of the technical peer review, to be deemed *Acceptable* and/or within the Competitive Range may be subject to auditing of their facilities and Quality Assurance and Quality Control (QA/QC) capabilities. The decision to audit specific facilities will be made by the Project Officer. If audits are performed during the negotiations, the results of the audits will be a factor in final selection for award of a contract. Offerors, including proposed subcontractors, will be requested to make all non-proprietary records, including previous regulatory inspection records, and staff available in response to a pre-award site visit or audit by the NICHD or its designee. **Due to timeline requirements, pre-award site visits may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.**

TECHNICAL EVALUATION CRITERIA:
The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance. ***See Appendices 3S and 3T for sample evaluation factor definitions.***

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO - Additional Proposal Instructions – OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF TECHNICAL PROPOSALS.

1. GENERAL

The Selection of an offeror for contract award will be based on an evaluation of proposals against the factors and corresponding subfactors. The factors in order of importance are: technical, cost and past performance. The technical factors and corresponding subfactors are listed in order of importance. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that vendor/offeror whose quote/proposal provides the best overall value to the Government. The Government will use an adjectival rating scale on all quotes/proposals.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP/RFQ. The merits of each quote/proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP/RFQ. Vendors/Offerors must submit information sufficient to evaluate their quotes/proposals based on the detailed factors listed below.

Although technical factors are of paramount consideration in the award of the contract, past performance, and cost/price are also important to the overall contract award decision. As proposals become more equal in terms of technical merit and past performance, the cost or price becomes more important.

The Government intends to make an award to that vendor/offeror whose quote/proposal provides the best overall value to the Government.

2. COST/PRICE EVALUATION

Vendor/Offeror(s) cost/price quote/proposal will be evaluated for reasonableness against the rates of their respective GSA contract under FAR Part 8.4. Although price reasonableness has been established for the labor categories under the GSA Federal Supply Schedule IDIQ contract; the cost/price analysis based on the level of experience and expertise being proposed under a labor category may deem a price to be unreasonable to perform the requirement(s).

3. EVALUATION OF OPTIONS

It is anticipated that any contract awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

4. TECHNICAL EVALUATION RATINGS

The Government shall evaluate proposals in accordance with the factors and criteria established in the RFP/RFQ. The rating definitions provided below will be used for the evaluation of each technical evaluation factor and subfactor and to assign each proposal with an overall rating. Quotes/Proposals shall be evaluated using adjectival rating system – definitions of the ratings are shown below:

Outstanding (O):

Significantly exceeds most or all solicitation requirements for this factor or subfactor or overall. Response exceeds a "Good" rating. The risk of unsuccessful contract performance is extremely low.

Good (G):

Fully meets all solicitation minimum requirements and exceeds many of the solicitation requirements for this factor or subfactor or overall; OR exceeds a small number of the minimum requirements but to a significant degree or in a valuable way for this factor or subfactor or overall. Response exceeds an "Acceptable" rating. The risk of unsuccessful contract performance is very low.

Acceptable (A):

Fully meets all solicitation minimum requirements for this factor or subfactor or overall. Areas where the proposal exceeds the minimum solicitation requirements, if any, are of little or no value to the Government. The risk of unsuccessful contract performance is low.

Marginal (M):

Less than "Acceptable." Does not meet all solicitation minimum requirements for this factor or subfactor or overall. The proposal indicates a superficial or vague understanding of the program goals and the methods, resources, schedules and/or other aspects essential to contract performance. The risk of unsuccessful contract performance is moderate.

Unacceptable (U):

Technical proposal has many or significant deficiencies and/or substantial omissions for a factor or subfactor or overall AND/OR the proposal demonstrates a lack of understanding of the program goals, methods, resources, schedules and/or other aspects essential to contract performance. The risk of unsuccessful contract performance is high.

5. TECHNICAL EVALUATION CRITERIA

The technical evaluation criteria for the review of each quote/proposal are specified below; listed in order of importance.

(CORs shall consider two approaches when listing the criteria: 1) Specific task area(s); or 2) General criteria area(s) (i.e. Technical/Management Approach; Personnel; Facilities))

- Approach #1 – narrative should include any/all sub-criteria relevant to an offeror/vendor satisfying the task area; or

- Approach #2 – the sub-criteria to each criterion should be in descending order of importance.

6. OTHER FACTORS (COR)

❑ HUMAN SUBJECT EVALUATION
❑ EVALUATION OF DATA SHARING
❑ EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH
❑ EVALUATION OF FOREIGN CURRENCY OFFERS, FAR 52.225-17

❑ PAST PERFORMANCE FACTOR
❑ EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION
❑ SUBCONTRACTING PROGRAM EVALUATION CRITERIA
Use when additional evaluation of the offeror's subcontracting program is warranted and desired.
❑ 508 COMPLIANCE (Consult with your IC's 508 Compliance Officer)
❑ SOFTWARE DEVELOPMENT
❑ COST COMPARED TO TECHNICAL

Appendix 3D: Reporting Requirements and Deliverables (Attachment 3)

PROJECT TITLE

RFP/RFQ NUMBER

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer (CO), unless otherwise specified.

a. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES ARTICLE in SECTION F.

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and prepared in accordance with the format described below.

Format of Cover page: All reports shall include a cover page prepared in accordance with the following format:

- Contract Number and Project Title
- Period of Performance Being Reported
- Contractor's Name and Address
- Author(s) • Date of Submission • Delivery Address

(Check all that apply) (The PO should provide any additional specific information to be reported under the contract for each applicable report.)

❑ (1) Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

❑ (2) Quarterly Progress Report

(a) This report shall include a [❑ summation of the monthly progress reports ❑ a description of the activities during the reporting period] and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

(b)A monthly report will not be submitted for the final month of a quarter.

❑ (3) Semi-Annual Progress Report

(a) This report shall include a [❑ summation of the monthly progress reports ❑ a description of the activities during the reporting period] and the activities planned for the ensuing reporting period. The

initial report will be submitted for the first full six months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months.

(b)Monthly and quarterly reports will not be submitted the month the semi-annual report is due.

❑ (4) Annual Progress Report

This report includes a summation of the results of the entire contract work for the period covered. An Annual Progress Report will not be required for the period when the Final Report is due. A [❑ Monthly ❑ Quarterly ❑Semi-Annual] Report shall not be submitted when an Annual Report is due.

❑ **Use the below narrative if the Project Officer requests a draft annual report.**

The Contractor shall provide the Project Officer and Contracting Officer with _____ copies of the Annual Progress Report in draft form [❑ in accordance with the DELIVERIES Article in SECTION F of this contract ❑ _____ calendar days prior to the delivery date for the Final Version of the Annual Report.] The Project Officer will review the draft report and provide the Contracting Officer with comments within _____ calendar days after receipt. The Annual Progress Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

❑ Use in all contracts for clinical research involving human subjects:

(5) Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of the contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the Final Report.

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001, applies. If this contract is for Phase 3 clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions.

In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

❑ (6) Final Report

This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An annual report will not be required for the period when the Final Report is due.

❑ **Use the below narrative if the Project Officer requests a draft final report.**

The Contractor shall provide the Project Officer and Contracting Officer with _____ copies of the Final Report in draft form [in accordance with the DELIVERIES Article in SECTION F of this contract _____ calendar days prior to the completion date of this contract.] The Project Officer will review the draft report and provide the Contracting Officer with comments within _____ calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

❑ (7) Summary of Salient Results (required for all R&D contracts)

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

b. Other Reports and Deliverables

In addition to the above reports, the following are considered other reports and deliverables under this contract and are identified in the Statement of Work. A listing is included in the DELIVERIES Article in SECTION F.

(Check all that apply)

❑ **Human Subjects IRB Annual Report** (Form OMB No. 0990-0263-formerly Optional Form 310)

❑ **Invention Report Requirement** - Use when Patent Rights (FAR 52.227-11 or 52.227-13) may be included in the contract.

❑ **Source Code and Object Code** - Use when software is used, produced, modified or enhanced

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

SECTION D – PACKAGING, MARKING, AND SHIPPING

NOTE: If known at the time of solicitation, this section should be tailored according to the specifications given by the Program Official in the event certain deliverables must be specially packaged and marked. Examples of deliverables which would be included in this category could include: tissue samples packed in dry ice, animals in special containers, infectious agents, pharmaceuticals, etc.

Checked boxes indicate that these items must be addressed in Section D of the solicitation. The Contract Specialist should work with the Project Officer to ensure that any related clauses are also inserted into the solicitation.

- ❑ Cannot be determined at this time
- ❑ Temperature controlled environment is required
- ❑ Shipments will be time sensitive/time critical
- ❑ International shipping will apply
- ❑ Shipping insurance is required
- ❑ Hazardous Materials shipping is applicable
- ❑ Other (list as necessary) _____
- ❑ N/A to this solicitation

ARTICLE F - DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the STATEMENT OF WORK Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract. will be required to be delivered F.o.b. Destination as set forth in FAR 52.24735, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract]:

a. Technical Progress Reports (SAMPLE TEMPLATE)

Item	Reports	Recipients	Delivery Schedule
1.	Monthly Progress Report	1 elec. copy to PO and CO	The first report is due on/before _____. Thereafter, each report is due on/before the 15th of each month following each reporting period.
2.	Quarterly Progress Report	1 elec. copy to PO and CO	The first report is due on/before _____. Thereafter, each report is due on/before the 30th of each month following each reporting period. Monthly reports will not be submitted the month the quarterly report is due.
3.	Semi-Annual Progress Report	1 elec. copy to PO and CO	The first report is due on/before _____. Thereafter, each report is due on/before the 30th of the month following each 6-month period. Monthly and quarterly reports will not be submitted the month the semi-annual report is due.

4.	Annual Progress Report	1 elec. copy to PO and CO	The first report is due on/before _____. Thereafter, each report is due on/before the 30th of the month following each anniversary date of the contract. Monthly, quarterly, and semi-annual reports will not be submitted the month the annual report is due.
5.	Annual Utilization Report	1 copy to CO	Due on/before the 30th of the month following each anniversary date of the contract.
6.	Final Invention Statement	1 copy to CO	Due on/before completion date of the contract.
7.	All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 copy to OPERA	As required by FAR Clause 52.227-11.
8.	Draft Final and Final Report and Summary of Salient Results	1 elec. copy to PO and CO	Draft Final Report is due ___ calendar days prior to the completion date of contract. Final Report is due on/before the completion date of the contract

b. Other Reports and Deliverables

Item	Deliverables	SOW Reference	Recipients	Delivery Schedule
1.	Draft and Final Study and Validation Protocols with SAP	[insert SOW paragraph or task reference, i.e. 1.a.6.]	1 elec. copy to PO	15 calendar days prior to initiating each study.
2.	Working Technical Standard Operating Procedures (SOPs)	[insert SOW paragraph or task reference]	1 elec. copy to PO	15 calendar days prior to initiating each study.
3.	Draft Study and Validation Study Reports with Statistical Analyses (SA)	[insert SOW paragraph or task reference]	1 elec. copy to PO	Within 30 calendar days after completion of each study.
4.	Draft and Final Stability Study Protocols	[insert SOW paragraph or task reference]	1 elec. copy to PO	15 calendar days prior to initiating each study.
5.	Draft Stability Study Report	[insert SOW paragraph or task reference]	1 elec. copy to PO	Within 30 calendar days after completion of each study.
6.	All animals as described in Section C, and progeny	[insert SOW paragraph or task reference]	To be specified 60 days prior to contract completion	At contract completion
7.	Vaccine	[insert SOW paragraph or task reference]	To be specified 60 days prior to contract completion	At contract completion

Appendix 3E: Additional Technical Proposal Instructions & Additional Business Proposal Instructions (Attachment 4)

The sections listed below are optional. Work with your CS to determine if any are applicable.

ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS, FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS

PROJECT TITLE
RFP/RFQ NUMBER

It is strongly recommended that offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These additional Technical Proposal instructions reflect the requirements of the RFP/RFQ and provide specific instructions and formatting for the Technical Proposal. While Section L.2.b. of the RFP/RFQ provides a generic set of Technical Proposal instructions applicable to all NIH R&D solicitations, these instructions are tailored to the specific requirements of the RFP/RFQ. The information requested in these instructions should be used to format and prepare the Technical Proposal, and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested here.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, and attachments, the Technical Evaluation Criteria in Section M, and the RFP/RFQ as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors, and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the entire Technical Proposal is _____ pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS
GENERAL NOTES (if not applicable, delete)

List any uniform technical assumptions related to the requirements of the contract that will assist offerors in the preparation of their Technical Proposals. For example, for RFPs/RFQs with advanced product development requirements, it may be appropriate to indicate that NICHD is aware of the uncertainty of the regulatory pathway in terms of FDA guidance for the development of therapeutics, etc, but that offerors are still required to address preclinical development, production, testing and characterization of candidates in compliance with existing FDA requirements.

SECTION 1:

1) PROPOSAL TITLE PAGE. Include RFP/RFQ title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
2) PROJECT OBJECTIVES, NIH FORM 1688
3) GOVERNMENT NOTICE FOR HANDLING PROPOSALS
4) PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)

5) TABLE OF CONTENTS
6) MANDATORY QUALIFICATION CRITERIA (delete if not applicable)

The Mandatory Qualification Criteria (MQC), identified in SECTION M of this solicitation, must be met at the time of receipt of the Original Proposal at the time of receipt of the Final Proposal Revision submission.

Documentation to support compliance with the MQC must be provided for the offeror and any proposed subcontractor(s). Include all information relevant to the MQC in this clearly marked section of your Technical Proposal. Include copies of all materials necessary to demonstrate that you have met the MQC.

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3-page maximum)

Provide instructions to offerors to include a brief overview of the proposed program/service. For example:

Provide a brief description of the proposed project, including:

1) A 1-2 sentence summary describing the vaccine concept the offeror is proposing to advance.
2) A summary describing the scope of product development activities proposed.
3) A description of the activities to be performed by the offeror and those that shall be provided by any proposed subcontractor, including the identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with desired qualifications and experience.
4) A brief description of the facilities and other resources to be made available by the offeror and any proposed subcontractors.

Helpful Tip: Key personnel may be established in the solicitation under the key personnel clause and reflected in the evaluation factors.

If applicable, provide instructions to include a milestone summary and Gantt chart.

SECTION 3: TECHNICAL PLAN/APPROACH

For each major SOW function or group of functions for which potential offerors should be evaluated, provide instructions for offerors to demonstrate, describe, etc. their technical approaches, scientific rationale, proposed methodologies, proposed plans and procedures, etc. to carrying out each task. The order of items should be presented in a manner that will provide the most meaningful presentation for reviewers to evaluate technical merit of proposals, and does not necessarily have to follow the order of items in the SOW.

Helpful Tip: If there are industry standards for performance or quality that can be referenced, try to include them.

It may be appropriate to include additional “Sections” of instructions for proposed plans/approaches that are tailored to the specific requirements of the solicitation. For example, **QUALITY CONTROL/QUALITY ASSURANCE SYSTEM/PLANS, and PROTOCOL IMPLEMENTATION AND OVERSIGHT** might be more appropriate as individual Sections rather than as sub-sections under **TECHNICAL PLAN/APPROACH.**

SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL (edit instructions as appropriate)

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of scientific and technical personnel, including scientific

and technical personnel of all proposal subcontractors. Clearly identify who is to be assigned as Key Personnel. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the RFP/RFQ, and include experience with projects of similar scope, size and complexity carried out by the offer and any proposed subcontractors over the past 5 years.

In the Personnel categories below, identify specific expertise and qualifications required such as clinical trials experience, biohazard training, animal handling and training, experience with NICHD Category A-B pathogens, statistical leadership experience, etc.

1) Principal Investigator (PI): include experience and qualifications of the PI to plan, manage, and direct the activities to be carried out under this contract:
2) Scientific and Technical Personnel:

SECTION 5: FACILITIES, EQUIPMENT AND OTHER RESOURCES (edit instructions as appropriate)

The Technical Proposal should document availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work, including:

1) Location and features of facilities including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).

2) Identification and description of ALL support resources (including Information Technology systems) which will be required to effectively complete the SOW.

Identify any other desired information or provide a description of requested supporting documents. This section may also include instructions to demonstrate ability to comply with safety and safety training requirements.

SECTION 6: PROJECT MANAGEMENT (edit instructions as appropriate)

1) Provide a plan for project organization, staffing, and management in relation to the planning, initiation, implementation, conduct, monitoring and completion of tasks identified in the Statement of Work. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants. Provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s). Include a chart of the proposed organizational/management structure for the project.

2) Describe the project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan must include a description of the quality control methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements.

3) Outline how the PI (or Project Manager) will communicate with the Project Officer and Contracting Officer and how the PI (or Project Manager) will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

SECTION 7: OPTIONS (if not applicable, delete)

List each Option that the Government reserves the right to exercise, for example:

1) To increase the services/quantities provided for in the base period of the Statement of Work;

2) To add new services/quantities different from the base period of the Statement of Work;
3) To extend the period of performance (either for increased or new services/quantities).

Provide instructions on what offerors are to include in the Technical Proposal to demonstrate/document capabilities and plans for the activities to be carried out under each Option, as well as personnel, project management, and facilities, equipment and other resources to perform the work under the Option(s).

SECTION 8: OTHER CONSIDERATIONS

Section L of the RFP/RFQ provides minimum documentation requirements for the following items. The required information described in Section L should be assembled together, in the following clearly marked sections of the Technical Proposal. Refer to Section L of the RFP/RFQ for specific requirements. Read each section below carefully. In some cases, offerors may be asked to provide documentation which is in addition to the minimum requirements identified in Section L.

Delete all that do not apply, below. If additional information is desired, please add below.

1) Human Subjects

Section L of the RFP/RFQ specifies the minimum documentation requirements for Human Subjects use. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should document all information necessary to evaluate Human Subject use.
2) Care of Live Vertebrate Animals

Section L of the RFP/RFQ specifies the minimum documentation requirements for Animal Welfare compliance. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should document all information necessary to evaluate Animal Welfare issues.

3) Biological Agents or Toxins

The Technical Proposal should include a plan for biohazard safety and security requirements.

4) Obtaining and Disseminating Biomedical Research Resources

Section L of the RFP/RFQ specifies the minimum documentation requirements for this element. The Technical Proposal should document all information necessary to evaluate this issue.

5) Sharing Research Data (Plan)

Section L of the RFP/RFQ specifies the minimum documentation requirements for Data Sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for Data Sharing as required by this RFP/RFQ.

6) Sharing of Model Organisms for Biomedical Research (Plan)

Section L of the RFP/RFQ specifies the minimum documentation requirements for Model Organism sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for sharing Model Organisms as required by this RFP/RFQ.

7) Information Technology (IT) Systems Security

Section L of the RFP/RFQ specifies the minimum documentation requirements for IT Systems security. All related documentation should be included in the Technical Proposal in this clearly marked section. The Technical Proposal should include a plan for IT Systems security as required by this RFP/RFQ.

Back to Appendix list

Appendix 3F: Advance Understandings (as needed) (Attachment 5)

ADVANCE UNDERSTANDINGS

PROJECT TITLE
RFP/RFQ NUMBER

❑ There are **NO** Advance Understandings applicable to this solicitation.

❑ The below Advance Understandings are applicable to this solicitation.

This section is used to specify requirements that the successful offeror must agree to before contract award. These Advance Understandings will become part of the resulting contract. Examples include confidentiality, intellectual property, publications, and any agreements that involve third party suppliers of materials for testing/screening under the contract. The NICHD Information Resources Management Branch will work with Program Divisions to develop appropriate language and requirements.

Appendix 3G: Potential Source List (Attachment 6)

POTENTIAL SOURCE LIST

Provide a list of potential sources that have the requisite capabilities to submit a proposal. Include the organization name, complete address, the point of contact (POC), telephone and fax numbers, and e-mail address.

Organization Name		Organization Name	
Address		Address	
POC		POC	
Telephone		Telephone	
Email		Email	
Organization Name		Organization Name	
Address		Address	
POC		POC	
Telephone		Telephone	
Email		Email	
Organization Name		Organization Name	
Address		Address	
POC		POC	
Telephone		Telephone	
Email		Email	

It is anticipated that Offerors could be any of the following organizational type(s):
(Check all that apply)

- ❑ Commercial
- ❑ Non-Profit
- ❑ Educational
- ❑ State Government

- ❑ Other _____

Back to Appendix list

Appendix 3H: Sources Sought Notice (Attachment 7)

Sources Sought Notice Information

Introduction

This is a Small Business Sources Sought (SBSS) notice. This notice is not a request for proposals and does not commit the Government to award a contract now or in the future. No solicitation is available at this time. The purpose of this notice is to obtain information regarding: (1) the availability and capability of all qualified small business sources; (2) whether they are small businesses; HUBZone Small Businesses; Service-disabled, Veteran owned Small Businesses; 8(a) Small Businesses; Veteran-owned Small Businesses; Woman-owned Small Businesses; or Small Disadvantaged Businesses; and (3) Their size classification according to the North American Industry Classification System, (NAICS) Code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible or through full and open competition. All size organizations are encouraged to respond. Small business organizations must have their size status certified by the small business administration. The NAICS code is _____ with a size standard of _____ employees.

Description

Using the Background and Introduction section of the Statement of Work, provide two to three paragraphs which describe the supplies and/or services to be provided. Include the estimated FTEs (in hours) from the IGCE if appropriate.

Potential sources must demonstrate and document the following in their capability statements:
Enter necessary capability

Capability statements submitted as a result of this announcement should demonstrate the offerors' qualifications and experience, specifically providing evidence as to their capability to perform this requirement, with particular attention to the following:
Enter how technical capability or qualifications will be evaluated

Personnel/Management: adequacy, appropriateness and relevance of expertise, experience, qualifications, and availability of the key professional and technical staff with a project of similar size, scope, and complexity.

Past Performance: Past performance is considered essential. In addition to demonstrating that they have met the above qualifications, interested parties must identify at least three other projects of similar size and complexity.

Interested organizations that believe they possess the capabilities necessary to undertake this project should submit electronic copies of their capability statement, addressing the areas above. Please limit responses to five (5) pages or less. Any proprietary information should be so marked. Written capability statements should be received by the Contracting
Officer by no later than _____ AM/PM Eastern Time on _____. Capability statements must identify the business status of the organization (i.e. educational institution, non-profit, large business, small business, 8 (a), or other corporate or non-corporate entity). NO COLLECT CALLS WILL BE ACCEPTED. RESPONDENTS MAY SUBMIT THEIR CAPABILITY STATEMENTS VIA E-MAIL. Information submitted should be pertinent and specific in the technical area under consideration, on each of the following qualifications (1) Experience: an outline of

previous projects, specific work previously performed or being performed and any in-house research and development effort; (2) Personnel: Name, professional qualifications and specific experience of scientist, engineers and technical personnel who may be assigned as principal investigator and/or project officer: (3) Facilities: Availability and description of special facilities required to perform in the technical areas under consideration. A statement regarding industrial security clearance. Any other specific and pertinent information as pertains to this particular area of procurement that would enhance our consideration and evaluation of the information submitted.

Appendix 3I: List of Potential Technical Review Members (Attachment 8)

POTENTIAL TECHNICAL REVIEWERS

Provide a list of potential technical reviewers. Include the organization name, complete address, the point of contact (POC), telephone and fax numbers, and e-mail address.
Note: *At least 50% of those proposed must be COR certified.*

Organization Name		Organization Name	
Address		Address	
POC		POC	
Telephone		Telephone	
Email		Email	
Organization Name		Organization Name	
Address		Address	
POC		POC	
Telephone		Telephone	
Email		Email	
Organization Name		Organization Name	
Address		Address	
POC		POC	
Telephone		Telephone	
Email		Email	

It is anticipated that Offerors could be any of the following organizational type(s):
(Check all that apply)

- ❑ Commercial
- ❑ Non-Profit
- ❑ Educational
- ❑ State Government
- ❑ Other _____

Back to Appendix list

Appendix 3J: List of Government-furnished Property (Attachment 9)

LIST OF GOVERNMENT-FURNISHED PROPERTY

Appendix 3K: Justification and Approval (J&A) (Attachment 10)

Justification and Approval for Sole Source (J&A) (Template)

Completion Instructions: HHS has established a standard template for preparation of a Justification and Approval for Sole Source (J&A) for non-Federal Supply Schedule acquisitions exceeding the simplified acquisition threshold. Operating Divisions (OPDIVs) shall prepare the template in accordance with these completion instructions. (NOTE: *The Project Officer (PO) has responsibility for completing all of the information items included in the template, with any necessary assistance from the cognizant Contracting Officer (CO) and Contract Specialist (CS) -- especially for items 3.(b), 4., 6., 7., 8. and 10. listed below.*

The instructions for preparing a J&A are specified in "red" and should be deleted prior to processing the document for review and approval. Also, do not include the completion instructions in the completed document.

A completed J & A must contain all of the applicable bolded headings in the order specified. Place the required information directly next to, or under, the applicable heading. If a heading does not apply to a specific J & A, indicate "not applicable" (N/A) next to it. Reference and attach any additional information necessary to support the J & A.

Justification and Approval for Sole Source
"Source Selection Information – see FAR 2.101 and 3.104"

1. **Identification of the agency and contracting activity.** Provide the following information:

a. **Federal agency and contracting activity. HHS.** Enter the OPDIV name after "HHS."

b. **Sponsoring organization.** Specify the name of the OPDIV's major subcomponent organization (such as Institute, Center, Office, or Division) and lower-tier organization, if applicable, that is sponsoring the proposed acquisition.

c. **Project Officer information.** Provide the following information:

- **Project Officer name.**
- **Mailing address.**
- **E-mail address.**
- **Telephone number.**

2. **Nature and/or description of the action being approved.** Provide the following information:

a. **Acquisition purpose and objectives.** State the nature, purpose, and objective(s) of the acquisition and the overall program of which it is a part. Identify the authorizing program legislation, as applicable.

b. Project background. Specify any project background that is important to understanding the acquisition and the need it will satisfy. If the project is a continuation or renewal of an ongoing contract/order, provide the current contract/order number and indicate: (i) the name of the incumbent or predecessor contractor; (ii) the period of performance; (iii) total dollar amount obligated to date; and (iv) whether the initial and any subsequent awards were competed and, for any sole-source or limited competition awards, the basis for the approved J & A.

3. Description of the supplies or services required to meet the agency's needs (including the estimated value). Provide the following information:

a. Project title. Enter the project title as it will appear in the solicitation and resultant contract/order.
b. Project description. Provide a brief (i.e., half-page or less) narrative description of the project. [NOTE: A Statement of Work (SOW) may be referenced and attached in lieu of providing a project description. The term SOW, as used throughout this document, includes "Specification," "Statement of Objectives" (SOO), and "Performance Work Statement (PWS)."]

Provide the following information:

- **Requirement type.** Check the appropriate box:
  □ Research & development (R&D)
  □ R & D support services
  □ Support services (non-R&D)
  □ Supplies/equipment
  □ Information technology (IT)
  □ Construction
  □ Architect-engineer (A & E) services
  □ Design-build
  □ Other (specify): _____

- **Type of action.** Check the appropriate box:
  □ New requirement
  □ Follow-on
  □ Other (specify): _____

- **Proposed contract/order type.** Check all that apply:

  □ Firm-fixed-price
  □ Other fixed-price (specify, e.g., fixed-price award-fee, fixed price incentive-fee): _____
  □ Cost-plus-fixed-fee
  □ Other cost reimbursement (specify, e.g., cost-plus-award-fee, cost-plus-incentive-fee): _____
  □ Time and materials
  □ Indefinite delivery (specify whether indefinite quantity, definite quantity, or requirements): _____
  □ Other (specify): _____
  □ Completion Form □ Term form

- **Acquisition identification number.** Specify the requisition number, proposed solicitation number, or other acquisition identification number, if applicable.

c. Total estimated dollar value and performance/delivery period.
Specify the total estimated dollar value of the acquisition, inclusive of options, and the total performance/delivery period.

4. Identification of the statutory authority permitting other than full and open competition. Check the applicable block below based on the acquisition circumstance.

❑ **This acquisition is conducted under the authority of 41 United States Code (U.S.C.) 253(c)(__) as set forth in Federal Acquisition Regulation (FAR) 6.302- __.** Check this block for an acquisition that is based on the authority used to support the noncompetitive acquisition (see FAR 6.302-1 through 6.302-7). Enter the appropriate U.S.C. exception and FAR citation in the spaces provided.

❑ **This acquisition is conducted under the authority of section 4202 of the Clinger-Cohen Act of 1996.** Check this block for an acquisition that *is* based on the authority of the test program for commercial items – specifically section 4202 of the Clinger-Cohen Act of 1996 [see FAR 13.501(a)(1)(ii)].

❑ **This acquisition is conducted under the authority of the Services Acquisition Reform Act of 2003 (41 U.S.C. 428a).** Check this block for an acquisition that *is* based on the authority of the test program for commercial items – specifically the Services Acquisition Reform Act of 2003 [see FAR 13.500(e) and 13.501(a)(1)(ii)]. {NOTE: This authority may only be used when acquiring items in support of a contingency operation or to facilitate the defense against or recovery from nuclear, biological, chemical, or radiological attack [see FAR 13.500(e)(1)]}.

5. Demonstration that the proposed contractor(s) unique qualifications or the nature of the acquisition requires use of the authority cited. Provide the following information, as applicable:

a. Name and address of the proposed contractor(s). Enter the (i) name and address of the proposed sole source contractor or (ii) names and addresses of the contractors to whom the proposed acquisition will be limited.

b. Nature of the acquisition and proposed unique qualifications of the contractor(s). Describe fully why only the designated supply/service will meet the sponsoring organization's needs and the contractor's unique qualifications to provide the requirement. Discuss how those qualifications or the nature of the acquisition relate to the authority cited.

6. Description of the efforts made to ensure that offers are solicited from as many potential sources as practicable. Indicate whether a notice was or will be publicized as required by FAR Subpart 5.2 and, if not, which exception under FAR 5.202 applies. Explain the efforts taken (or to be taken) to solicit as many potential offerors as possible, particularly if the basis of the J & A is the authority cited in FAR 6.302-2 (i.e., unusual and compelling urgency) or 6.302-6 (i.e., national security.) (NOTE: Proposed acquisitions for other than full and open that are expected to exceed $25,000 must be announced in Contract Opportunities, previously known as FedBizOpps, hosted on System for Award Management (SAM) website, whether or not a sources sought notice or other presolicitation notice was issued previously.) Indicate whether a Contract Opportunities notice will be published as required by FAR Subpart 5.2 and, if not, state the exception in FAR 5.202 that applies.

7. Determination by the Contracting Officer that the anticipated cost/price to the Government will be fair and reasonable. Provide a statement, based on the specific circumstances and type of acquisition proposed, that reflects the steps the CO will take (including documentation) regarding the fairness and reasonableness of the cost/price of the contract/order prior to its award.

The determination shall cite, at a minimum: (a) the type of cost or pricing information that will be obtained from the proposed contractor(s) and whether it will be certified – see FAR 15.406-2; (b) the type and extent of cost or price analysis anticipated; and (c) whether an audit will be performed.

8. **Description of the market research conducted (see FAR Part 10) and the results, or a statement of the reasons market research was not conducted.** Describe the market research that was conducted and the results of that effort (see FAR Part 10). Examples of market research include: (a) issuing a sources sought announcement in Contract Opportunities; (b) publishing a request for information in technical or scientific journals or business publications; (c) reviewing literature published by qualified organizations; (d) contacting knowledgeable acquisition and program officials in Government and industry regarding market capabilities; and (e) convening a presolicitation conference to exchange information with the marketplace. If market research was not conducted, provide an explanation. (NOTE: Issuing the FBO notice under Item 6. above does not, in and of itself, constitute market research.)

9. **Any other facts supporting the use of other than full and open competition.** Cite any other factors not mentioned earlier in the justification as to why the requirement cannot be competed. Also, if applicable:

(a) explain why technical data packages, engineering descriptions, or a SOW suitable for full and open competition have not been developed or are not available for a competitive acquisition;
(b) when the requirement can only be satisfied by one responsible source for a follow-on acquisition [see FAR 6.302-1(a)(2)(ii)], indicate whether there would be (i) unacceptable delays in fulfilling the agency's requirements and/or (ii) duplication of cost by award to another organization and, if so, provide an estimate of the cost duplication and how it was derived;

(c) if the justification is based on unusual and compelling urgency (see FAR 6.302-2), indicate (using data, estimated cost, or other rationale) the extent and nature of the harm that the sponsoring organization would incur and/or the unacceptable delays that would occur. Also, explain whether the proposed period of performance is the minimum acceptable period necessary to meet mission requirements, including why a shorter period is not advisable. If future extensions are anticipated, indicate what steps will be taken to encourage and solicit competition. (NOTE: The length of a contract or order awarded under these circumstances cannot exceed one year unless approved by the OPDIVHead of the Contracting Activity.)

10. **Listing of sources, if any, that expressed, in writing, an interest in the acquisition.** List the sources, if any, that have expressed an interest, in writing, in the acquisition and provide an explanation of why they are not being considered. If no expressions of interest have been received, enter "No other sources have expressed an interest, in writing, in the proposed acquisition." Any responses, such as capability statements, received in response to a published notice (e.g., a sources sought notice or request for information), must be evaluated. Include all evaluations as an attachment to the J & A, along with the names of the individuals who participated in the review and a copy of the communication to each organization that responded. In addition, document any requests made to the CO by interested organizations for a copy of the solicitation or SOW with the following information: (a) the name of and contact information for the organization that submitted the request; (b) any communications with the requestor; and (c) the disposition of the request. (NOTE: Normally, a J & A should be routed for review and approval after the Contract Opportunities notice period (see Item 6.) has expired. However, in extenuating circumstances (e.g., when substantial administrative, funding, or technical delays or issues are anticipated or occur that could jeopardize timely review and approval of a J & A), a J & A that does not require Senior Procurement Executive (SPE) review and approval may be routed for review (but not approval) prior to completion of the synopsis period. The OPDIV HCA must provide prior written/electronic

concurrence with such an action. In no event shall the justification be forwarded to the approving official before expiration of the synopsis period and before the results of any expressions of interest in the acquisition have been evaluated (other than requests for a copy of the solicitation) and documented. Further, a solicitation may only be released to an intended source after approval of a J & A.)

11. **Statement of the actions, if any, the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the required supplies or services.** Provide a brief statement as to whether or not there are future plans to acquire the same type of supplies or services, e.g., further extensions or renewals by competitive or other means. If subsequent acquisitions are anticipated, cite actions taken, or anticipated, to avoid continued noncompetitive acquisition of the requirement in the future and a schedule for accomplishing those actions. (NOTE: This may involve recompeting a successor requirement at a logical juncture in the phasing of the project or "breaking out" segments of the requirement to facilitate competition, where feasible.) If no actions have been or will be undertaken to overcome barriers to competition for future acquisitions, so indicate and provide an explanation.

12. **Program office certification.** The program officials cited shall complete the information required below and sign the certification in the blocks provided.

    This is to certify that the portions of this justification that have been developed by the undersigned program office personnel, including supporting information and/or data verifying the Government's minimum needs, schedule requirements and other rationale for other than full and open competition, are accurate and complete.

Official	Name & Title	Signature	Date
Project Officer			
Project Officer's Immediate Supervisor			
Head of the Sponsoring Program Office			

13. **Contracting Officer Certification.** The CO shall complete the information required below and sign the certification in the block provided. [NOTE: The CO's signed certification may serve as approval of a J & A over $150,000 but not exceeding $650,0001, depending on OPDIV procedures.)
    1 This dollar range is current as of the date of issuance of interim acquisition policy memorandum No. 2008-03, but is subject to change – see FAR 6.304(a)(1) and 13.501(a)(2)(i). See HHSAR 306.304(a)(1) and 313.501(a)(2)(i) for additional information regarding CO approval of a J & A in this dollar range.

    This is to certify that the justification for the proposed acquisition has been reviewed and that to the best of my knowledge and belief the information and/or data provided to support the rationale and recommendation for approval is accurate and complete.

Official	Name & Title	Signature	Date
Contracting Officer			

14. **Chief of the Contracting Office and Head of the Contracting Activity signature(s).** The Chief of the Contracting Office (CCO), if applicable, and the HCA shall indicate review of, and concurrence with, any J & A over $650,000[2] by providing the information required below and signing in the applicable block.

2 This review and concurrence requirement is applicable to the dollar ranges over $650,000 cited in the FAR, specifically: (i) over $650,000 but not exceeding $12.5 million; (ii) over $12.5 million but not exceeding $62.5 million; and (iii) over $62.5 million – see FAR 6.304(a)(2) through (4) and 13.501(a)(2)(ii) through (iv). See HHSAR 306.304 and 313.501(a)(1)(iii) for additional information regarding CCO/HCA review of and concurrence with a J & A in these dollar ranges. These dollar ranges are current as of the date of issuance of interim acquisition policy memorandum No. 2008-03, but are subject to change.

Official	Name & Title	Signature	Date
Contracting Officer			
Head of the Contracting Activity			

15. **Competition Advocate signature.** The designated OPDIV Competition Advocate (CA), upon acceptance of the rationale provided in the J & A, shall complete the information required below and sign in the block provided as the approving official for any J & A over $650,000 but not exceeding $62.5 million[3]. However, if the CA does not meet the requirements of FAR 6.304(a)(3)(ii) for a J & A over $12.5 million, but not exceeding $62.5 million, an individual other than the CA shall exercise the approval authority.

    The signature of the CA, or that of an individual meeting FAR 6.304(a)(3)(ii) requirements for a J & A over $12.5 million, but not exceeding $62.5 million, shall serve as concurrence on any J & A over $62.5 million that requires the approval of the HHS SPE.

3 This approval authority is applicable to the following dollar ranges cited in the FAR, specifically: (i) over $650,000, but not exceeding $12.5 million; and (ii) over $12.5 million, but not exceeding $57 million – see FAR 6.304(a)(2) and (3) and 13.501(a)(2)(ii) and (iii). See HHSAR 306.304(a)(2) and (3) and 313.501(a)(ii) and (iii) for additional information regarding this approval authority, including when the CA does not meet the requirements of FAR 6.304(a)(3)(ii). These dollar ranges are current as of the date of issuance of interim acquisition policy memorandum No.2008-03, but are subject to change.

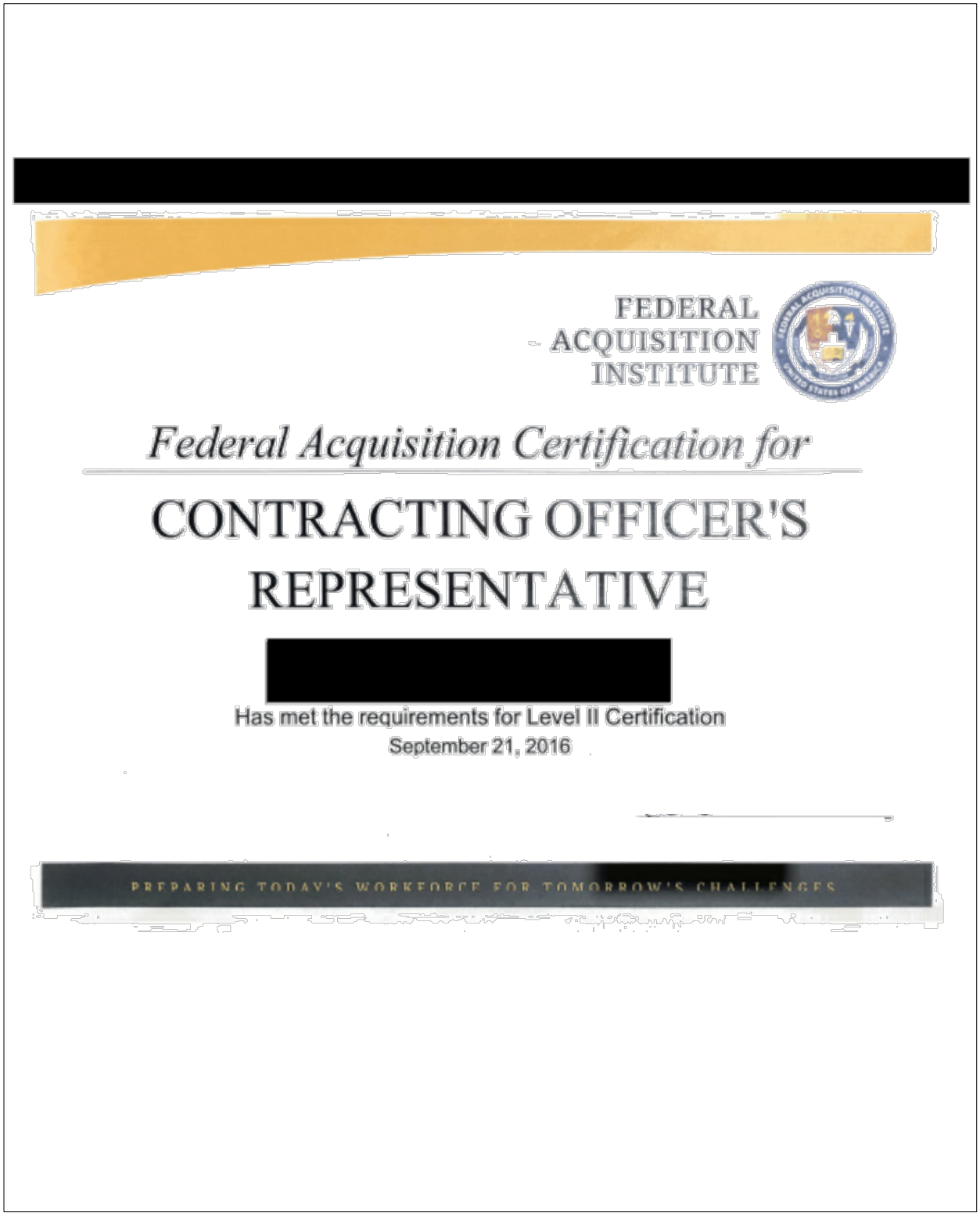
Official	Name & Title	Signature	Date
Competition Advocate			

16. **HHS Senior Procurement Executive signature.** The HHS SPE, upon acceptance of the rationale provided in the J & A, shall complete the information required below and sign in the block provided as the approving official for any J & A over $62.5 million[4].

Official	Name & Title	Signature	Date
HHS Senior Procurement Executive			

4 This dollar range is current as of the date of issuance of interim acquisition policy memorandum No. 2008-03, but is subject to change – see FAR 6.304(a)(4) and 13.501(a)(2)(iv). See HHSAR 306.304(a)(4) and 313.501(a)(2)(iv) for additional information regarding SPE approval of a J & A in this dollar range.

Appendix 3L: COR Certification (Attachment 11)


[redacted]

FEDERAL ACQUISITION INSTITUTE

Federal Acquisition Certification for

CONTRACTING OFFICER'S REPRESENTATIVE

[redacted]

Has met the requirements for Level II Certification

September 21, 2016

PREPARING TODAY'S WORKFORCE FOR TOMORROW'S CHALLENGES

Appendix 3M: Independent Government Cost Estimate (IGCE) (Attachment 12)

INDEPENDENT GOVERNMENT COST ESTIMATE (IGCE)

Attachment 13
IGCE-Sample.xlsx

SUMMARY OF PROPOSED COSTS

TITLE RFQ Number		BASE YEAR Date Through Date		Option One Option Yr. 1 Date Through Date		Option Two Option Yr. 2 Date Through Date		TOTAL
Direct Labor - Percent of Effort:								
		$0		$0		$0		$0
		$0		$0		$0		$0
		$0		$0		$0		$0
		$0		$0		$0		$0
		$0		$0		$0		$0
		$0		$0		$0		$0
		$0		$0		$0		$0
		$0		$0		$0		$0
		$0		**$0**		**$0**		**$0**
Travel		$0		$0		$0		$0
Materials and Supplies		$0		$0		$0		$0
Equipment/Computers		0		0		0		$0
		0		0		0		$0
Other Direct Costs		0		0		0		$0
Total Other Direct Costs		**$0**		**$0**		**$0**		**$0**
GSA Materials Usage Charge	3%	$0	3%	$0	3%	$0	3%	$0
Total Proposed Cost (DL, ODC, GSA)		**$0**		**$0**		**$0**		**$0**

- Not all organizations allocate indirect cost in the same way. It is important that you use the indirect rate structure applicable to your organization. For example, if you have a three tier indirect rate structure, then you will use a three tier structure when proposing indirect costs.

  Generally, Universities and Non-Profits have fringe benefit and G&A (or sometimes called F&A) rates, while For-Profit Companies can have various indirect rates such as fringe benefits, overhead, G&A, etc.

  The base for overhead costs includes direct labor and fringe benefits. Please modify if your base is different.

Appendix 3N: Office of Small and Disadvantaged Business Utilization (HHS 653 - Small Business Review Form) (Attachment 13)

Office of Small and Disadvantaged Business Utilization
HHS 653 – Small Business Review Form

OSDBU Control Number: _____ Date Received: _____

A. Project Information

1. Solicitation Number: _____

Acquisition Instrument Proposed/Contract Type:
[ ] Contract No: _____
[ ] Departmental IDIQ No: _____
[ ] GSA Schedule No: _____
[ ] GWAC Contract No: _____
[ ] HHS BPA (Strategic Sourcing):
[ ] Posted/Identified on HHS OPDIV Forecast

2. Acquisition Office and OPDIV:

CO/CS/COR/PA Name:

Location (Bldg. and Room):

Contact Information (Telephone, Fax and E-mail):

3. Brief description of services or products to be procured:

4. Total Estimated Value (Including Options): $ _____ Base: $ _____ Options: $ _____

5.a. Period of Performance (including Options) or Delivery Date: _____.
5.b. The RFP/RFQ will be posted within ___30 days; ___90 days; ___6 months after the OSDBU Small Business Specialist review.

B. Project Considerations

6. NAICS Code: _____

Dollars: _____

No. of Employees: _____

8. Bundling/Consolidation:

[ ] N/A: *Below established threshold: FAR 7.104(d)(2)*

Yes No
[ ] [ ] Is requirement consolidated?
If yes, attach supporting documentation.

[ ] [ ] Contracting Officer's Representative (COR) certified the bundling status.

7. [ ] New Requirement [ ] Recompetition [ ] Similar Requirement

Acquisition History:

Previous Contract Number: _____ Award Date: _____
Total Amount of Contract Award: _____
Contractor Name: _____
Contractor Size/Type of Ownership: _____
Previous/NAICS Code/Size Standard: _____
Number of Offers from Small Business: _____
Comments: _____

9. Efforts made to locate sources within last 12 months:

CO	SBS	
[ ]	[ ]	Review of Prior or Similar Acquisition
[ ]	[ ]	Contracting Officer (Comments Attached)
[ ]	[ ]	Program Office (Comments Attached)
[ ]	[ ]	Sources Sought Notice (Copy Attached)
[ ]	[ ]	Market Survey (Copy Attached)
[ ]	[ ]	Consult HHS Small Business Specialist
[ ]	[ ]	Central Contractor Registration (CCR)
[ ]	[ ]	Other: _____

10. Acquisition Method(s)

[ ] 8(a) Set-Aside/Competitive/Sole Source (SBA Offering Letter)
[ ] HUBZone Set-Aside/Competitive/Sole Source
[ ] Service-Disabled Veteran-Owned (SDVOSB) Set-Aside
[ ] Women-Owned (WOSB) Set-Aside
[ ] Economically Disadvantaged Women-Owned (EDWOSB) Set-Aside
[ ] Total Small Business Set-Aside
[ ] Partial Small Business Set-Aside
[ ] Urban Indian Organization (P.L. 94-437) and Buy Indian Act (25 USC 47) – IHS HCA Authorization required.
[ ] JOFOC (Authority): _____
[ ] No Reasonable expectation of obtaining 2 or more SB offers.
[ ] Other (explain): _____

11. Synopsis:

[ ] Yes (FEDBIZOPPS)
[ ] No. Per FAR 5.202 _____
[ ] Other: _____

12. Other Considerations that apply to the Solicitation:

Yes	No		Yes	No	
[ ]	[ ]	Subcontracting Plan *(if no, see instructions)*	[ ]	[ ]	SDB Plan
[ ]	[ ]	Green Contracting Considerations			

Other: _____

C. Project Review & Approval

13. Cognizant Contracting Official:

_____ _____
Signature Date

14. OSDBU Small Business Specialist:
[ ] Concur [ ] Non-concurrence:

_____ _____
Signature Date

15. SBA Procurement Center Representative:
[ ] Concur [ ] Non-concurrence:

_____ _____
Signature Date

HHS Form 653 (Revised October 2011)

HHS 653 - SMALL BUSINESS REVIEW FORM - Comments
HHS OSDBU Small Business Specialist Comments: **Name:** _____ **Date:** _____
SBA Procurement Center Representative Comments: **Name:** _____ **Date:** _____

HHS Form 653 (Revised October 2011)

HHS 653- SMALL BUSINESS REVIEW FORM INSTRUCTIONS

PROJECT INFORMATION (ITEMS 1 – 5)

1. Enter the solicitation number. Indicate acquisition instrument/contract type by checking appropriate box:

   - Contract number for a Modification
   - HHS IDIQ number
   - GSA Schedule number
   - GWAC Contract number
   - HHS Strategic Sourcing BPA number

   In accordance with PL 100-656, each OPDIV is required to post its Forecast Information http://www.hhs.gov/about/smallbusiness/forecasthome.html

2. Enter Contracting Officer/Specialist (CO/CS), Contracting Officer Representative (COR) or Purchasing Agent's Name, OPDIV, Building, Room, Telephone, Fax and e-mail.

3. Enter the item/service description or project title.

4. Enter the total estimated dollar value of the contract, including all options. If necessary attach information.

5. a. Enter the estimated period of performance, including any option periods, using (mm/dd/yy to mm/dd/yy) format.

   b. Indicate whether the solicitation will be issued within 30 days, 90 days or 6 months after the small business review

PROJECT CONSIDERATIONS (ITEMS 6 – 12)

6. Enter appropriate North American Industrial Classification System (http://www.census.gov/eos/www/naics/index.html). Enter either the applicable Number of Employees or Average Annual Receipts for the specified NAICS.

7. Check box for "New Requirement" if this is a first time acquisition for products/services.

   Check box for "Recompetition" if this is a recompetition of a previous acquisition.

   Check box for "Similar Requirement" if this is an acquisition that is similar in scope and technical requirements.

   Enter history. For Type of Ownership, list SDB, 8(a), SB, WOSB, VOSB, SDVOSB or HUBZone as applicable. You may use the Central Contractor Registration (CCR- http://www.ccr.gov/).

8. Indicate response to Bundling/Consolidation. *[Note, FAR 7.104(d)(2) identifies threshold for applicability.]* If the total contract value is estimated below this threshold, check N/A. If this requirement is the result of consolidation or bundled requirements, the SBS must concur.

9. Check the appropriate box(es) indicating all resources utilized to identify potential sources that support the acquisition method recommended in Item 10. Include/Attach supporting documentation for each effort. *[Note: SBS will not accept market surveys conducted more than 12 months prior to date of this requirement.]*

10. CO/CS/COR/PA – Check the appropriate box(es) indicating the acquisition method determined. If the procurement is sole source, include a copy of the signed JOFOC & supporting documentation. The 653 is not to be submitted until the Presolicitation/Notice of Intent notice has closed and any capability statements received have been reviewed. If the procurement is 8(a) and $150,000 or more, include a copy of the SBA offering letter in accordance with FAR Part 19.804-2 (http://www.arnet.gov/far/loadmainre.html). For WOSB Set-Aside and EDWOSB Set-Aside, verify NAICS is included in WOSB Program applicability NAICS list www.sba.gov/wosb.

11. Check appropriate box and refer to FAR 5.202 to indicate the specific exemption.

12. CO/CS/COR/PA – Check yes or no where other considerations apply. See FAR 19.702(a)(1) and (2) to determine if a Subcontracting Plan is required. A Subcontracting Plan is required if the CO/CS/COR anticipates that the estimated cost may exceed $650,000 ($1,500,000 for construction). If NO for Subcontracting Plan and/or SDB Plan, attach the approved waiver and supporting documentation -See FAR 19.705-2(c). HHS SBS and SBA PCR concurrence is required.

PROJECT REVIEW & APPROVAL (ITEMS 13 – 15)

13. The Contracting Official (CO) who has the authority to bind the government will make a determination, sign and date.

14. The HHS SBS will sign, date and indicate concurrence or non-concurrence with the method of acquisition determined by the CO. If the HHS SBS does not concur, another method will be recommended (see SBS comments).

15. The SBA PCR shall sign and date this block to indicate concurrence or non-concurrence of the acquisition method determined by the CO. If the SBA PCR does not concur, the rationale will be documented on page 3 of this form and it will include a recommendation. If necessary, the SBA PCR will initiate an appeal process (SBA Standard Form-70) and forward supporting documentation to the CO.

NOTE: In order for the HHS Small Business Specialist to conduct a comprehensive review of each acquisition, at a minimum, the documentation forwarded by the CO/CS/COR/PA should include:

1. Completed HHS Form 653 signed by the Contracting Official
2. Completed Acquisition Plan (AP) or Request for Quote (RFQ) package. Package must include:
   a. The statement of work, including evaluation criteria and the Government cost estimate.
   b. Documentation which reflects market research conducted within the past 12 months.
   c. If 8(a) procurement $150,000 or greater, attach the SBA Offering Letter. You may visit SBA's website to identify the SBA District Office that corresponds to your contracting office (http://www.sba.gov/localresources/index.html).
3. A copy of the justification for other than small business consideration applicable to the subject acquisition plan.
4. A copy of the signed JOFOC, Presolicitation/Notice of Intent, any responses, and the review documentation of the responses.

HHS Form 653 (Revised October 2011)

Appendix 3O: Clearance/R&D Project Concept/Approval Documentation (Attachment 14)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Natic stitute of Diabetes and
Di e and Kidney Diseases

Memorandum

Date: November 16, 2016

To:

From:

Subject:

This memo requests permis ive conc review for the "Liver Tissue and Cell Distribution System (LTCD CDS contract with the University of Minnesota will end on June 28, Dr. errano has already obtained approval from the Director of NIDDK to recompe contract for five more years. The Office of Acquisitions at NIC has begun the p ss of recompetition, with the intent to issue a solicitation throug mpetition and to award a new follow-on contract by June 28, 2017.

The objective of the LT as been to provide access to human liver tissue and cells for strictly purposes IH investigators throughout the United States. The objective contin to be t ide an liver, in order to facilitate bridging the gap between anim esea an applicability. The service makes it possible to directly inves human atocytes and hepatic tissue in studies of cell biology, metabolism, gene re ion and disease conditions. Over the years, the LTCDS has provided hum ocytes primarily in culture and human liver tissue (primarily pathologic) quick frozen at the time of hepatic resection in the operating room during orthotopic or living related donor liver transplantation. In addition, the LTCDS has increasingly provided "normal" human hepatocytes in culture or normal liver tissue (primarily frozen), slides, and tissue blocks. Since its inception, hundreds of NIH funded investigators in the field of liver research have received thousands of liver tissue specimens and hepatocyte preparations

To address the limitation imposed on liver research by the lack of suitable normal and pathologic human liver tissue and cells, NIDDK established a contract for the procurement and distribution of liver tissue in September 1986. Throughout the ensuing years the LTCDS Program has been successfully outsourcing this to academic consortia and has competitively procured follow-on contracts with educational institutions. The service contract has been a reliable source of high quality liver tissue as well as isolated hepatocytes at a fraction of the cost charged by commercial sources, significantly reducing

the cost of NIH funded research.

A concept review of the anticipated research study is the first ste the pr ss of completing a full acquisition cycle. By this memorandum, w requ g a wai r of the external HHS concept review. Per the NIH Policy Manual 6 Initiation, Review, Evaluation and Award of Research and Develop R&D ntract that can be found at http://oma.od.nih.gov/manualchapters/contracts/63 , IC Director or designee may determine and document to the Contracting Offic nat a project concept review is not needed when the solicitation i compete or ex d a project that is within the scope of a current project that has been pr ly peer r wed.

Thank you for your consideration of this req

_____ _____

Program Director Signature Date

_____ _____

Contracting Officer Signature Date

_____ reby determine that an external concept review **is not needed** for subject acquisition.

Signed:

_____ _____

IC Director Signature Date

Appendix 3P: Contract Opportunities Draft Presolicitation Notices (Attachment 15)

Draft Presolicitation Notice

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), on behalf of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), plans to solicit proposals through full and open competition procedures from qualified organizations having the capability to support the Liver Tissue and Cell Distribution System (LTCDS), in order to facilitate the procurement, processing and distribution of liver tissues and cells to NIH funded investigators throughout the United States.

The mission of National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support research on many of the most serious diseases affecting public health. The institute supports much of the clinical research on the diseases of internal medicine and related subspecialty fields, as well as many basic science disciplines. Among these diseases are end-stage liver diseases. To understand the pathophysiology of these diseases, it is essential to provide researchers with access to liver tissue and cells from a variety of end-stage liver diseases, as well as normal livers. These specimens would not be available to researchers who work outside a liver transplant center.

To support this need, NIDDK established the Liver Tissue Cell Distribution System (LTCDS) in 1986, to facilitate the procurement, processing and distribution of liver tissues and cells to investigators throughout the United States. The incumbent contractor is the University of Minnesota.

The LTCDS provides to the scientific community human liver tissue collected from regional centers (with active liver transplant programs and human subjects approval) supplying portions of the resected pathologic liver for which the transplant is performed. Frozen or fresh tissue is available from other organizations for the usual forms of childhood and adult cirrhosis, fulminate liver failure, chronic rejection, and certain inborn errors of metabolism. In addition LTCDS provides "normal" human liver tissue (primarily frozen), slides, and tissue blocks, and rarely other liver cell types in culture.

LTCDS is to serve as a resource for investigators to obtain human liver tissue for scientific investigation. This liver tissue system:
1. Collects portions of liver removed from liver transplant recipients at surgery.
2. Collects and provides normal liver tissue to investigators if the tissue from organ donations cannot be used for the recipient because of size, state of anoxia, etc. (a very rare event).
3. Develops and maintains the capacity to retrieve, preserve, and deliver available tissues in such condition as will be useful to investigators conducting biomedical research projects at institutions throughout the United States.
4. Provides normal human hepatocytes in culture.

On average, each year, this system provides about 750 shipments of liver tissue (tissue, blocks and slides) and 150 shipments of hepatocytes (equivalent to about 7x10^9 hepatocytes).

The NIDDK requires an organization to provide the infrastructure for procurement and distribution of

liver tissues and cells from a variety of end-stage liver diseases and normal livers to basic scientific investigators. The requirement seeks to facilitate the distribution of discarded liver tissue to qualified investigators in order to stimulate research on liver diseases. Recipients of cells and tissue from diseased livers are primarily investigators whose projects have been vetted by the NIDDK grant process. Available supplies of isolated hepatocytes from normal liver currently dictate that these are provided only to investigators at the National Institutes of Health.

The scope of the program is comprised of procuring, isolating, purifying, preserving and distributing donor liver tissue, as well as reporting on this process. Donor tissue shall include whole or sectioned human liver tissue that is normal or shows pathology from a variety of liver diseases. This tissue shall be processed into liver tissue blocks (frozen, paraffin embedded), hepatocytes suitable for cellular and molecular studies, and other preparations.

To facilitate progress in liver research, to respond to the need of the investigators and to assess the evolution of the services, the contractor shall obtain periodic input from the scientific community regarding the provision of other liver specimens, particularly non-parenchyma cells.

Government supplied facilities include cryopreservation facilities and LTCDS IT systems.

The requirement shall consist of the following tasks:

1. Clinical tasks, focused primarily on procuring donor tissue in a clinical setting. Specifically, the requirement shall include obtaining informed consent of organ donors; building a synopsis of donor's medical history and laboratory data; collecting whole or partial livers; and delivering this to a biotech laboratory for further processing.

2. Technical tasks, focused primarily on the isolating, purifying, and preserving the liver tissue in a biotech laboratory setting. The primary objective for tissues prepared with cryopreservation or histology techniques is a preparation that clearly preserves characteristic structures and pathology. The primary objective for cells is to maintain a high rate of cell viability.

3. Order Management tasks, focusing primarily on distributing the tissue to basic investigators. The primary objective is to deliver specimens in excellent condition; process financial accounting information; and track the production process. The system shall receive user requests; review and prioritize requests; maintain a fee schedule; receive and process payments; and communicate with investigators via a website and to form, and be guided by, an external Coordinating Committee.

4. Reporting tasks, focusing primarily on collecting, analyzing and reporting data on the tasks described above. Specifically, data shall be presented on demographics, metrics, quality control, cost information, inventories, transaction activity and benefits of the program, such as the citations of publications resulting from this service. These data shall be analyzed and presented in graphic form. The requirement includes the ability to customize data queries, export query results to spreadsheet applications and

graphically summarize and print query results. This task shall support the Coordinating Committee's strategic decision-making by providing the following types of information: review of operating procedures, quality control procedures, tissue processing procedures, information storage and management procedures, and operating policies ensuring equitable access to contract services.

A completion type cost-reimbursement contract using NAICS code 541712- Research and Development in the Physical, Engineering and Life Sciences (except Biotechnology), is contemplated. On behalf of NIDDK, NICHD intends to award a contract on or about August 27, 2017, consisting of a base period and our 12 month option years. This acquisition is a competitive renewal of HHSN276201200017C, titled "Liver Tissue and Cell Distribution Systems (LTCDS)."FAR Part 15 procedures will be used to compete the procurement with full and open competition. It is anticipated the Request for Proposals (RFP) will be released on or about March 31, 2017 on the FedBizzOpps website.

RFP No. NIH-NIDDK-DDN-2017-5 will be available electronically on or about 15 days from the date of this posting. You can access the RFP through the FedBizOpps (URL: http://fedbizopps.gov). All information required for the submission of a proposal will be contained in or accessible through the RFP package. Responses to the RFP will be due 45 days from the release date. NIDDK anticipates an award date on or before September 8, 2017. NIDDK will consider proposals submitted by any responsible offeror.

This announcement does not commit the Government to award a contract.

Appendix 3Q: FISMA Certification - Information Security Program Requirements (Attachment 16)

Note: Consult your Information System Security Officer (ISSO) and Privacy Officer for current version.

INFORMATION SECURITY PROGRAM REQUIREMENTS
Checklist and Certification (2/2009)

RFP No: _____ Pre Solicitation Review Date: _____
Contract No: _____ Pre-Award Review Date: _____

Project Title: _____

Contracting Officer: _____
Name and Contact Information

Contract Specialist: _____
Name and Contact Information

PRE-SOLICITATION

☐ **INFORMATION SECURITY IS APPLICABLE** and the following information is required for RFP preparation:

A. INFORMATION TYPE

☐ **Administrative, Management and Support Information:**

☐ **Mission Based Information:**

B. SECURITY CATEGORIES AND LEVELS

Confidentiality:	○ Low	○ Moderate	○ High
Integrity:	○ Low	○ Moderate	○ High
Availability:	○ Low	○ Moderate	○ High
Overall:	○ Low	○ Moderate	○ High

C. POSITION SENSITIVITY DESIGNATIONS

The following position sensitivity designations and associated clearance and investigation requirements apply under this contract:

☐ **Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI).** Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

☐ **Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with MBI or LBI).** Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

☐ **Level 1: Non Sensitive (Requires Suitability Determination with an NACI).** Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

D. PROSPECTIVE OFFEROR NON-DISCLOSURE AGREEMENT

◉ Offerors **WILL NOT** require access to sensitive information in order to prepare an offer.

○ Offerors **WILL** require access to sensitive information in order to prepare an offer:

Description of sensitive information:

Select appropriate position sensitivity designation below.

○ **Level 6C: Sensitive - High Risk**
○ **Level 5C: Sensitive - Moderate Risk**

☐ **INFORMATION SECURITY IS NOT APPLICABLE for this RFP.**

CERTIFICATION: Based on the above, and contingent upon inclusion of all applicable RFP language prescribed in the NCI RFP Workform, we certify that the solicitation specifies appropriate security requirements necessary to protect the Government's interest and is in compliance with all Federal and DHHS security requirements.

_____ _____
Project Officer Signature Date

_____
Project Officer Typed Name

_____ _____
Information Systems Security Officer Signature Date

_____
Information Systems Security Officer Typed Name

INFORMATION SECURITY PROGRAM REQUIREMENTS
Checklist and Certification (2/2009)

RFP No: _____ Pre Solicitation Review Date: _____
Contract No: _____ Pre-Award Review Date: _____

Project Title: _____

Contracting Officer: _____
Name and Contact Information

Contract Specialist: _____
Name and Contact Information

PRE-AWARD

A. SYSTEMS SECURITY PLAN (SSP)

☐ **SSP Approved.** The SSP dated _____, submitted by the contractor has been reviewed by the Government, is considered acceptable, and should be incorporated into the awarded contract.

☐ This project requires a full SSP conforming to the NIST Guide for developing Security Plans for federal Information Systems http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf which must be submitted to the ~~NCI~~, ISSO no later than 90 calendar days after the effective date of this contract.

☐ The SSP submitted by the contractor does not meet the minimum requirements for IT Security in the following area(s):

[ ] Security Awareness Training
[ ] Access Control
[ ] Protection against data loss
[ ] Malicious Code Protection
[ ] Physical Security

A revised SSP shall be submitted no later than 90 calendar days after the assignment of task (eg. hosting a government website) that would require such a plan.

☐ No SSP is required for this work.

B. OFFEROR'S PROPOSAL

☐ Notwithstanding the information regarding the SSP, above, the offeror's proposal dated, _____, specifies appropriate security requirements necessary to comply with the Federal and Departmental policy.

☐ The offeror's proposal dated, _____, is deficient in the following areas:

_____
_____
_____

☐ No Award is recommended until the offeror submits additional information to resolve the deficiencies sited above.

☐ Award may be made contingent upon the inclusion of contract language stipulating the submission of additional information resolving the deficiencies cited above. This information must be submitted no later than 90 calendar days after the effective date of this contract.

CERTIFICATION: Based on the above, and contingent upon inclusion of all applicable Contract language prescribed in the ~~NCI~~ Contract Workform, we certify that the contract specifies appropriate security requirements necessary to protect the Government's interest and is in compliance with all Federal and DHHS security requirements.

_____ _____
Project Officer Signature Date

_____
Project Officer Typed Name

_____ _____
Information Systems Security Officer Signature Date

_____
Information Systems Security Officer Typed Name

Back to Appendix list

Appendix 3R: Acquisition Alert (2019-01)

ACQUISITION ALERT 2019-01

HHS Acquisition Review

TO: Heads of Contracting Activity

FROM: Andrea Brandon //s//
Deputy Assistant Secretary for Grants and Acquisition Policy
And Accountability and Senior Procurement Executive

SUBJECT: HHS Acquisition Review Pilot Program

EFFECTIVE DATE: November 29, 2018

Purpose:

The purpose of this memorandum is to extend the HHS Acquisition Review Pilot Program

Applicability:

This guidance and implementation instructions set forth in this memorandum are applicable to all contract actions. All acquisition programs and projects across HHS are eligible to participate in the pilot as established with Acquisition Alert 2018-03.

Roles and Responsibilities:

It is the HCA's responsibility to ensure widest distribution of this notice throughout HHS staff and operating divisions and to update an applicable policies and procedures to reflect this guidance.

Guidance:

The HHS Acquisition Review Pilot Program was established for the period of September 10, 2018 through January 9, 2019 and outlined in acquisition alert 2018-03. In order for both HHS and the OPDIVs of HHS to achieve the best results of the pilot initiative to streamline acquisition reviews, the pilot program will be extended through September 30, 2019.

HHS awards the majority of our contracts during the third and fourth quarter of each fiscal year. This is often necessary due to the federal budget and funding process. The current Acquisition Review Pilot period occurs when not many acquisitions occur. In order to gain a larger sampling of HHS acquisitions and determine if the pilot can become operation and streamline the acquisition reviews while ensuring transparency and accountability the pilot has been extended through September 30, 2019.

NIH Guidance for Implementing the HHS Acquisition Plan/Acquisition Strategy Review Pilot Program

(Acquisition Alert 2018-03, and 2019-01 effective September 10, 2018, through September 30, 2019)

Acquisition Alert 2018-03 implements the HHS Acquisition Review Pilot Program, which increases the review thresholds for Acquisition Plans and Acquisition Strategies during the pilot period, September 10, 2018, through January 9, 2019.[1,2] Acquisition Alert 2019-01 extends the pilot to September 30, 2019. At the conclusion of the pilot period, we return to the old review thresholds. HHS/OAP will evaluate the data from the pilot program to determine if the increased review thresholds become permanent.

ACQUISITION STRATEGIES	
Program/Project Total Lifecycle Cost	**Approval Level**
< $50M	OA Director
≥ $50M - < $100M	Head of the Contracting Activity, NIH
≥ $100M - < $150M	Deputy Director for Management, NIH
≥ $150M	HHS/Office of Acquisition Policy

ACQUISITION PLANS	
Total Dollar Amount	**Approval Level**
SAT Threshold - $20M	One level above the Contracting Officer
> $20M - < $50M	OA Director
≥ $50M - $150M*	Head of the Contracting Activity, NIH
> $150M	HHS/OAP
High Risk Acquisitions Regardless of Dollar Amount[3]	HHS/OAP
Special Interest Acquisitions Regardless of Dollar Amount[4]	HHS/OAP

* Informational copies of APs > $50M but ≤ $150M will be provided to HHS/OAP by DAPE.

11/30/18

Back to Appendix list

Appendix 3S: Evaluation Factors - Adjectival Ratings and Risk Definitions

ADJECTIVAL	DESCRIPTION/DEFINITION
Outstanding (O)	Significantly exceeds most or all solicitation requirements for this factor or subfactor or overall. Response exceeds a "Good" rating. The risk of unsuccessful contract performance is extremely low.
Good (G)	Fully meets all solicitation minimum requirements and exceeds many of the solicitation requirements for this factor or subfactor or overall; OR exceeds a small number of the minimum requirements but to a significant degree or in a valuable way for this factor or subfactor or overall. Response exceeds an "Acceptable" rating. The risk of unsuccessful contract performance is very low.
Acceptable (A)	Fully meets all solicitation minimum requirements for this factor or subfactor or overall. Areas where the proposal exceeds the minimum solicitation requirements, if any, are of little or no value to the Government. The risk of unsuccessful contract performance is low.
Marginal (M)	Less than "Acceptable." Does not meet all solicitation minimum requirements for this factor or subfactor or overall. The proposal indicates a superficial or vague understanding of the program goals and the methods, resources, schedules and/or other aspects essential to contract performance. The risk of unsuccessful contract performance is moderate.
Unacceptable (U)	Technical proposal has many or significant deficiencies and/or substantial omissions for a factor or subfactor or overall AND/OR the proposal demonstrates a lack of understanding of the program goals, methods, resources, schedules and/or other aspects essential to contract performance. The risk of unsuccessful contract performance is high.
RISK LEVEL	**DECRIPTION/DEFINITION**
Very Low Risk	The proposal contains no deficiencies or weaknesses. Based on information provided, there is no doubt that the offeror demonstrates an exceptional understanding of the services required to meet or exceed most contract requirements. The highest quality of contract performance is anticipated.
Low Risk	The proposal contains no deficiencies and only a few minor weaknesses that do not require discussions. Based on the information provided, there is little doubt that the offeror demonstrates a high quality of understanding of the services required to meet or exceed some contract requirements.
Moderate Risk	The proposal contains no deficiencies and some weaknesses. Based on the information provided, the Offeror demonstrates an understanding of the services required to meet contract requirements.
High Risk	The proposal contains deficiencies and significant weaknesses. Based on information provided, there is doubt that the contractor understands the services required to meet the contract requirements. Requirement/services can be met only with major changes to the proposal.
Unacceptable Risk	Technical proposal has many deficiencies and/or gross omissions; failure to understand much of the scope of work necessary to perform the required tasks; failure to provide a reasonable, logical approach to fulfilling much of the government's requirements; failure to meet many personnel requirements in the solicitation. (When applying this adjective to a proposal as a whole, the technical proposal would have to be so unacceptable in one or more areas that it would have to be completely revised in order to attempt to make it other than unacceptable.)

Back to Appendix list

Appendix 3T: Evaluation Factors – Color and Numerical Scores Definitions

TABLE 2: Relationship Between Ratings and Definitions		
Color Codes	**Numerical**	**Definition**
Blue	90-100	Exceeds specified performance or capability in a beneficial way to the agency and has no significant weakness.
Green	80-89	Meets evaluation standards and any weaknesses are readily correctable or may just need clarification(s).
Yellow	70-79	Fails to meet evaluation standards; however, through exchanges and negotiations, any significant weaknesses and/or deficiencies are correctable.
Red	0-69	Fails to meet a minimum requirement of the RFP/RFQ and the deficiency is uncorrectable without a major revision of the proposal/quotation.

Step 4: Solicitation

NIH Optimize Acquisitions

1.0 Introduction

The purpose of this document is to outline steps in the Solicitation process for the Offices of Acquisitions at the National Institutes of Health, which encompasses:

a) Preparing and issuing requests for proposals (RFPs/RFQs) and requests for information (RFIs);
b) Exchanging information with industry (and/or academic institutions) prior to receipt of proposals; and,
c) Receiving proposals and information.

2.0 Purpose

In general, the purpose of a solicitation is to ensure that all qualified offerors are given the opportunity to compete for Government contracts. The solicitation communicates the Government's requirements to prospective contractors and to solicit proposals or quotes. At a minimum, solicitations shall describe the Government's requirement, anticipated terms and conditions that will apply to the contract, information required in the offeror's proposal, and the criteria that will be used to evaluate the proposal and their relative importance.

3.0 Roles and Responsibilities

Contracting Officer's Representative (COR): The COR is responsible for assisting the CS in completing all the steps within the Solicitation process.

Contracting Officer (CO) / Contract Specialist (CS): The CO/CS is responsible for completing all the steps within the Solicitation process and will consult with the COR as necessary.

4.0 Expected Outcome

To receive proposals and/or quotations in response to a solicitation defining the requirements established by the Government. In some instances, the Solicitation timeline may be impacted due to unexpected changes or market conditions.

5.0 Associated Documents

- Request for Information (RFI)
- Pre-solicitation synopsis
- Solicitation Notice
- Solicitation

Step 5A: Evaluation and Negotiation (Research & Development (R&D))

NIH Optimize Acquisitions

1.0 Introduction

The purpose of this document is to outline the steps for the Evaluation and Negotiation (R&D) of proposals for the Offices of Acquisitions at the National Institutes of Health.

2.0 Purpose

In general, the purpose of Evaluation and Negotiation (R&D) is to select the proposal(s) that represent the best value to the Government and ensure fair, objective, and uniform peer review of research and development contract technical proposals.

During Evaluation and Negotiation, the following key principles need to be followed:

- No conflicts of interest exist.
- Evaluation is in strict accordance with the evaluation criteria in the RFP.
- Proposals are evaluated against standards, not each other.
- All source selection data and information is considered confidential and is protected.
- The Contracting Officer shall control all communications with the offeror(s).

3.0 Roles and Responsibilities

Contracting Officer's Representative (COR): As the subject matter expert, conduct administrative review of all technical proposals for compliance with the requirements in the solicitation and bring any issues which raise concern to the attention of the CO and Scientific Review Officer (SRO). Ensure there are no conflicts of interest with the proposals and comply with instructions provided by the SRO.

Contracting Officer (CO) / Contract Specialist (CS): Ensure that proposals are evaluated based solely on the factors and subfactors contained in the solicitation (10 U.S.C. 2305(b)(4)(C) and 41 U.S.C. 3703(c)); and control exchanges with offerors in accordance with regulations and policies.

Peer Review Panel (R&D): Independently review and evaluate all technical proposals and determine strengths, weaknesses, deficiencies, and risks according to the technical evaluation criteria in the solicitation. Ensure no conflicts of interest with proposals received and comply with instructions provided by the SRO.

Scientific Review Officer (SRO): Lead and coordinate the Peer Review process for the R&D Contract Technical Proposals received in accordance with 42 CFR Part 52h. Responsibilities during the peer review and evaluation process include, but are not limited to, identifying and recruiting reviewers in accordance with 42 CFR Part 52h.4(c); screening potential reviewers for conflicts of interest; safeguarding confidentiality of materials; convening and conducting pre-review and review meetings; and preparing, signing, and submitting the Technical Evaluation Report (TER) in accordance with policies and procedures.

4.0 Expected Outcome

Completion of the Evaluation and Negotiation (R&D) process which will provide a basis for source selection to determine overall best value for the R&D services required by the Government.

5.0 Associated Documents

- **Evaluation Review Package**
  The SRO will provide the evaluation review package to the panel members to conduct the Peer Review. The evaluation review package may include:
  - **Solicitation (RFP) Package**
  - **Solicitation Amendments**
  - **Technical Proposals**
  - **Evaluation Relationship** (Advice/Instructions to assist with rating/scoring proposals)
  - **Evaluation Definition Sheet** (Terms and Definitions to be used as part of rating the proposals)
  - **Technical Evaluation Sheet**
  - **Conflict of Interest Guidance and Definition**
  - **Conflict of Interest Certification Form**

Step 5B: Evaluation and Negotiation (Non-Research & Development)

NIH Optimize Acquisitions

1.0 Introduction

The purpose of this document is to outline the steps for the Evaluation and Negotiation (Non-R&D) of proposals for the Offices of Acquisitions at the National Institutes of Health.

2.0 Purpose

In general, the purpose of Evaluation and Negotiation (Non-R&D) is to select the proposal(s) that represent the best value to the Government. During the Evaluation and Negotiation process, the following key principles need to be followed:

- No conflicts of interest exist.
- Evaluation is in strict accordance with the evaluation criteria in the RFP.
- Proposals are evaluated against standards, not each other.
- All source selection data and information is considered confidential and is protected.
- The Contracting Officer shall control all communications with the offeror(s).

3.0 Roles and Responsibilities

Contracting Officer's Representative (COR): Ensure that all strengths, weaknesses and/or deficiencies identified by technical panel members are valid based on the technical requirements outlined in the solicitation; assist the CS in completing all steps of the Evaluation and Negotiation process (as needed); and provide recommendation for overall best value and selection.

Contracting Officer (CO) as the Source Selection Authority (SSA): Establish an evaluation team, tailored for the particular acquisition, that includes appropriate contracting, legal, logistics, technical, and other expertise to ensure a comprehensive evaluation of offers.

CO / Contract Specialist (CS): Ensure that proposals are evaluated based solely on the factors and subfactors contained in the solicitation (10 U.S.C. 2305(b)(4)(C) and 41 U.S.C. 3703(c)); and control exchanges with offerors in accordance with regulations and policies.

Technical Evaluation Panel (TEP): Perform the technical evaluation of all proposals in response to the solicitation (and all amendments), guided by the TEP Chair in accordance with the evaluation review package.

TEP Chair: Responsible for providing a summary of the evaluation report, which may include a narrative of the strengths and weaknesses for each proposal, documentation of reference checks, summary of each panel member's evaluation/score and consensus by factor, overall rankings, individual panel member's evaluation, and signature if the panel members indicate concurrence with the content of the consensus report.

4.0 Expected Outcome

Completion of the Evaluation and Negotiation (Non-R&D) process which will provide a basis for source selection to determine overall best value for services, supplies and equipment required by the Government.

5.0 Associated Documents

Evaluation Review Package

The TEP chair will provide the evaluation review package to the evaluation panel members to conduct the technical evaluation. The evaluation review package may include:

- **Solicitation (RFQ/RFP) Package**
- **Solicitation Amendments**
- **Technical Proposals**
- **Evaluation Relationship** (Advice/Instructions to assist with rating/scoring proposals)
- **Evaluation Definition Sheet** (Terms and Definitions to be used as part of rating the proposals)
- **Technical Evaluation Sheet**
- **Conflict of Interest Guidance and Definition**
- **Conflict of Interest Certification Form**

Step 6: Source Selection

NIH Optimize Acquisitions

1.0 Introduction

The purpose of this document is to outline the steps for Source Selection for the Offices of Acquisitions at the National Institutes of Health.

2.0 Purpose

The objective of source selection is to select the proposal(s) that represent(s) the best value for the Government using FAR Part 15 (Contracting by Negotiation).

The source selection authority (SSA) decision shall be based on a comparative assessment of proposals against all source selection criteria in the solicitation. While the SSA may use reports and analyses prepared by others, the source selection decision shall represent the independent judgment of the SSA. The source selection decision shall be documented and include the rationale for any business judgments and tradeoffs made or relied on by the SSA, including benefits associated with additional costs. Although the rationale for the selection decision must be documented, that documentation need not quantify the tradeoffs that led to the decision.

3.0 Roles and Responsibilities

Contracting Officer's Representative (COR): The COR assists in the preparation of draft versions of the Source Selection Determination. The COR also provides the recommendation(s) of Program.

Contracting Officer (CO): The CO is designated as the SSA, unless the agency head appoints another individual for a particular acquisition or group of acquisitions.

Contract Specialist (CS): The CS is responsible for drafting the Source Selection Determination as well as working with the COR to ensure the document reflects the overall best value for the Government.

COR Supervisor: The COR's supervisor is responsible for review and recommendation.

Budget Officer: The budget officer is responsible for certifying availability of funds.

Executive Officer (EO): The EO is responsible for review and recommendation, if applicable, per the internal process of the IC.

IC Director/Division Director: The IC Director or Division Director reviews and concurs with the Source Selection Determination, if applicable, per the internal process of the IC.

Source Selection Authority (SSA): The SSA selects the source or sources whose proposal is the best value to the Government.

4.0 Expected Outcome

The source identified and selected is based on the evaluations of the proposals and exchanges and is the overall best value for services, supplies and equipment required by the Government.

5.0 Associated Documents

Recommendation for award package

- Program Recommendation
- Summary for Award Decision (See Appendix 6A), if applicable
- Source Selection Determination

Appendix 6A: Sample Summary of Award Decision Routing Sheet

Summary of Award Decision Routing Sheet

Date Prepared	Solicitation Number	Contract Number(s)

A. PROJECT TITLE

B. ATTACHED DOCUMENTATION

☐ Source Selection Determination ☐ Program Recommendation

C. CONTRACTOR(S) SELECTED FOR AWARD

Name(s) of Contractor(s)	Proposed Principal Investigator(s)	Negotiated Total Contract Amount (Including all Options)	Total Period of Performance in Months (Base plus all options)

D. NAME OF CONTRACT SPECIALIST/CONTRACTING OFFICER	TELEPHONE	INITIALS

E. CONCURRING OR APPROVING OFFICIAL	NAME (TYPED)	SIGNATURE	DATE
Concur: Branch Chief, NICHD OA			
Concur: Director, NICHD OA			
Concur: Contracting Officer's Representative (COR)			
Concur: COR's Immediate Supervisor			
Certify: Budget Officer	See Section F for budget certification.		
Concur: Executive Officer			
Concur: Director, IC (if applicable)			

Source Selection Information - See FAR 2.101 and 3.104

Approve: Source Selecting Official			
F. FUNDING			
Budget Officer ONLY Designates Fiscal Year of Initial Obligation:			
FY _____ $ _____ Signature: _____ Date: _____ *Budget Officer certifies that the above funding is hereby made available in support of this acquisition.*			

G. Changes from the Original Acquisition Plan. Describe the extent and nature of any changes in scope and/or funding (IGCE) from the proposed contract award amount.

Source Selection Information - See FAR 2.101 and 3.104

Step 7: Award

NIH Optimize Acquisitions

1.0 Introduction

The purpose of this document is to outline steps for the Award process for the Offices of Acquisitions at the National Institutes of Health.

2.0 Purpose

The objective of the Award step is to award a contract to the successful offeror(s) representing the best value to the government, and designation of the COR. This step begins after all offers have been evaluated, any negotiations required have been concluded, and the Government has determined a successful offeror.

3.0 Roles and Responsibilities

Contracting Officer's Representative (COR): The COR supports the CO during the contract award and execution process.

Contract Specialist (CS): The CS prepares the contract and other award documents for the contract file.

Contracting Officer (CO): The CO awards a contract to the successful offeror(s) by providing them the executed contract or other notice of award; designates the COR using the COR Designation Memo; and notifies and debriefs unsuccessful offerors upon written request.

NBS (NIH Business System) Requisitioner: The NBS Requisitioner enters the requisition into NBS.

4.0 Expected Outcome

The award of a contract to the successful offeror(s).

5.0 Associated Documents

- Contract Document
- Requisition Authorization Form
- Debriefing Letter(s)
- COR Designation Memo (Download)

Step 8: Administration

NIH Optimize Acquisitions

1.0 Introduction

The purpose of this document is to outline the steps involved in the Administration process for the Offices of Acquisitions at the National Institutes of Health.

2.0 Purpose

The objective of the Administration process is to carry out overall contract management and technical oversight functions. Contract Administration involves those activities performed by Government officials after a contract has been awarded. It covers all activities between the Government and the contractor from the date of contract award until the work has been completed and accepted or the contract has been terminated, payment has been made, and all disputes have been resolved.

3.0 Roles and Responsibilities

Contracting Officer's Representative (COR): The COR shall serve as the technical liaison between the contractor and CO, and report any issues, concerns, or problems to the CO. The COR shall monitor performance and timely delivery of deliverables, as set forth in the contract. The COR is also responsible for review of invoices to determine that billing is commensurate with technical progress under the contract. The COR serves as the Contract Performance Assessment Reporting System (CPARS) Assessing Official Representative and is responsible for evaluating and reporting technical progress and final technical performance.

Contract Specialist (CS): The CS serves as the lead on all contract administration functions. The CS should work with the COR and contractor to ensure that the terms and conditions of the contract are being upheld by both parties. In addition, the CS shall review invoices and monitor expenditures throughout the period of performance. The CS is also responsible for supporting the COR and CO during the CPARS process.

Contracting Officer (CO): The CO will carry out the contract administration functions to monitor deliverables and reporting requirements, ensure a contractor is adhering to terms and conditions, monitor expenditures, and modify a contract, if applicable. As the CPARS Assessing Official, the CO is also responsible for finalizing CPARS ratings.

Contractor: The Contractor is responsible for contract performance, including furnishing the Government with all deliverables and progress reports as stated in the contract and submitting invoices in accordance with the terms and conditions of the contract.

NIH Business System (NBS) Requisitioner: The NBS Requisitioner is responsible for entering the requisition into NBS which allows the CS to generate the funding associated with any/all funding actions.

Office of Financial Management (OFM): The OFM is responsible for initially receiving and reviewing invoices for accuracy and availability of funds, prior to sending the invoice for processing by the CS/CO. Once the COR recommends the invoice for payment and the CO approves, the invoice is sent to OFM for release of payment to the contractor.

4.0 Expected Outcome

All contract administration functions are performed.

5.0 Associated Documents

- COR Designation Memo (See Appendix 8A)
- Kick-off Meeting Checklist (See Appendix 8B)
- Kick-off Meeting Agenda Template (See Appendix 8C)
- Letter of Intent for Exercising Options (See Appendix 8D)

Appendix 8A: Sample COR Designation Memo

The expected outcome of the Administration Phase is that all contract administration functions are performed.

DATE:

MEMORANDUM FOR [CORs (p*reviously* c*alled Project Officer)* Name, Title]

FROM: [*Contracting Officer*] [*Branch*], ASB, Office of Acquisition, NICHD

SUBJECT: Appointment of Contracting Officers Representative (COR) for
Contract Number: [*Insert Contract Number*]
Contractor Name: [*Insert Contractor Name*]
Contract Title: [*Insert Title*]

This memorandum appoints you as the Contracting Officers' Representative (COR) with respect to technical matters within the scope of the contractual instrument referenced above. As such, you are authorized to act on behalf of this office in all matters related to the monitoring and overseeing of the technical and programmatic aspects of the contract, subject to the limitations set forth in this appointment.

You and your immediate supervisor are requested to sign the last page of this memorandum and return it to this office within 7 calendar days to acknowledge your appointment as COR and your receipt of this memorandum.

You are not authorized or delegated the authority to take any actions other than those listed below, related to that of a technical representative of the Contracting Officer (CO). You do not have the expressed or implied authority, to direct the contractor to perform work under this contract other than the work formally specified in the contract. This appointment does not empower you to bind the Federal Government contractually. This right is reserved exclusively for warranted Contracting Officers. One copy of the contract, all modifications (if applicable) and Contracting Officer Authorizations (if applicable) are attached.

This delegated authority is effective immediately and shall continue through final acceptance of the subject contract work, contract closeout, or until specifically revoked or modified by the CO or his/her successor. Your authority as COR shall not be redelegated by you to another individual. Your release from these delegated responsibilities, other than a revocation initiated by the CO, will require a formal request from your supervisor for release, along with the name of a COR to be delegated these same responsibilities upon your release from this delegation. Upon receipt and approval of a COR change, the CO will initiate a Contract Modification. That replacement COR must have completed the required Federal Acquisition Certification for Contracting Officers' Technical Representative (FAC-COR) certification training.

All personnel engaged in contracting and related activities shall conduct business dealings with the contractor in a manner above reproach in every aspect, and shall protect the U.S. Government's interests, as well as maintain its reputation for fair and equal dealings with all contractors.

If you have direct or financial interest or a personal relationship that would place you in a position where there is a conflict between your private interests and the public interests of the United States; then, promptly notify your supervisor and the CO of such conflict so that appropriate action may be taken. You shall avoid the appearance of such conflict in order to maintain public confidence in the U.S. Government's conduct of business with the private sector.

If you are in doubt as to the exact nature of your duties as the COR, contact the CO immediately. Working as a team will avoid problems. This delegation provides information regarding your responsibilities as a COR, as well as those activities you are specifically prohibited from performing as a COR.

YOUR RESPONSIBILITIES FOR THIS APPOINTMENT ARE OUTLINED BELOW:

General

- Serve as the Technical Representative of the Contracting Officer (CO) with the contractor;
- Ensure consistency among multiple PO's under a single contract when providing guidance to the contractor and evaluating the contractor's performance;
- Maintain a complete working file for the assigned contract.

Contract Familiarization

- Thoroughly familiarize yourself with the terms and conditions of the contract, the Statement of Work, this designation, and contractor responsibilities. Ensure that you have a copy of the contract and all formal changes and modifications readily available;
- Oversee technical contract matters including, but not limited to, issuing work authorizations that do not obligate the Government for reimbursement other than that already formally stated in the contract; maintaining working files; and inspecting and accepting contractor deliverables. However, you have no authority to obligate funds in the name of the U.S. Government. Orders that obligate funds must be executed by the CO;
- Ensure that the contractor meets the requirements as specifically stated in the contract;
- Give prompt attention to correspondence from the contractor that requires your response or signature;
- Fully read and understand regulations pertaining to ethics and standards of conduct, in accordance with the Procurement Integrity Act and other Agency requirements.

Changes/Modifications to the Contract

- Promptly furnish the CO any requests for change, deviation, or modification (whether generated by Government personnel or contractor personnel.) Furnish all supporting paperwork and documentation in connection with any requested change, deviation, or waiver;
- Assist the CO in identifying necessary changes or revisions to the contract. The COR will prepare Government estimates for Government generated changes and/or revisions; perform technical evaluations as required by the CO; assist the CO in the interpretation of scope of work, specifications and drawings and, assist in negotiations to the extent determined to be necessary to the CO. Minimum documentation includes a description of the effort/work to be performed, a Government cost estimate, and certified funding up to the full anticipated amount of the definitized

change or modifications;

- As required, provide technical support and assistance to the contractor regarding effort, shifting work emphasis between work area or tasks, filling in details, or otherwise assisting the contractor via technical advice, to accomplish the description of work as set forth in the contract. **The COR is not authorized to give any other type of change direction, if the change in any way affects (increases or decreases) the original contract time, effort, cost, or terms and conditions**;

- Immediately report instances where the contractor violated the provisions/terms/conditions/ scope of work of the contract, instances of unsatisfactory contractor work, or contractor relationships/customer service problems, to the CO;

- Make recommendations or advise the CO regarding poor or non-performed work.

Progress, Inspection and Acceptance

- Inspect and evaluate products (including reports and drafts) and services delivered by the contractor, and make recommendations to the CO regarding their acceptability;

- Monitor the contractor's use of key personnel and notify the CO of any changes in key personnel proposed by the contractor;

- Review the qualifications of proposed subcontractors and the appropriateness of subcontracting contract work, and make recommendations to the Contracting Officer regarding consent to the placement of subcontracts;

- Review the qualifications of proposed consultants and the appropriateness of consultant work, and make recommendations to the CO regarding consent to the placement of consultants;

- Monitor the use of, and report on Government-furnished property;

- Provide technical guidance to the contractor;

- If a project is likely to generate a potential claim or dispute, is of a high dollar value, high visibility, or is of a complex nature, then maintain a log documenting actions. This log may be useful at a later date in the event of a dispute or investigation;

- Discuss with the contractor any aspect of the contracted work that is lagging, be informed of problems, make recommendations for solutions, and remind the contractor of its responsibility to perform to the contract schedule within funded amounts;

- Ensure that the CO receives a copy of all correspondence between you and the contractor. These items are considered official contract file documentation and must be made part of the official contract file maintained by the CO;

- Complete the required post award interim and final evaluations of contractor performance in accordance with FAR 42.15, as described in Section G of the contract;
- Ensure proper distribution of final products and other information/data resulting from the contract

Claims and Requests for Equitable Adjustment

- Immediately provide all cost/technical proposals, requests for equitable adjustment, and claims to the CO if a contractor sends them directly to you;

- Since information from sources other than an offeror's or contractor's records may significantly affect the Government's negotiation position, you are prohibited from disclosing to a contractor anything having to do with the technical evaluation, the Government's cost estimate, the amount of funding available, any portion of audit reports, the Government's negotiation position, and other similar types of information, without receiving the explicit written concurrence of the CO. DO NOT make a final determination of contractor liability for loss or damage of Government Furnished Material (GFM) or Equipment (GFE).

Payments to the Contractor

- Review contractor's invoices (fixed-price contracts) or vouchers (cost-reimbursement type contracts); make recommendations to the CO for payments for work completed and related charges on the basis of the terms and conditions of the contract. **The COR is required to return the invoice to the CO with a recommendation for payment within 5 calendar days of receipt.** Only the CO is authorized to approve the expenditure of funds.

- Immediately forward the CO any invoices that you receive, if the contractor submits the invoices directly to the COR in lieu of following the specific instructions in **Section G** of the contract;

- Be cognizant that the total amount of payment invoiced should be is commensurate with technical progress for the period. Consideration should be given to the satisfactory completion of total estimated percentage of the work.

THIS APPOINTMENT DOES NOT AUTHORIZE YOU TO TAKE ANY ACTION THAT REQUIRES A CONTRACTING OFFICER'S WARRANT INCLUDING BUT NOT LIMITED TO THE FOLLOWING:

- Changing any of the contract's terms and conditions;

- Directing the contractor to perform work or make deliveries not specifically required under the contract;

- Making any type of contractual commitment or changing any terms or conditions of the contract;

- Waiving or relaxing, in any way, the Government's rights with regard to the Contractor's compliance with the specifications, price, delivery or any other terms or conditions of the contract;

- Granting deviations from or waiving any of the terms and conditions of the contract.

- Imposing or placing a demand upon the contractor to perform any task or permit any substitution not specifically provided for in the contract;

- Increasing the funded amount/ceiling amount/period of performance of the contract, or authorizing work beyond the funded amount/ceiling amount/period of performance of the contract, or authorize the expenditure of funds;

- Awarding, agreeing, or signing any contract, modification, delivery order, change order, or task order. All contractual agreements, commitments, or modifications, shall be made only by the Contracting Officer;

- Authorize the purchase of equipment or the furnishing of Government property, except as authorized under the contract;

- Authorizing subcontracting or the use of consultants;

- Approving shifts of funding between line items of the budget where costs are restricted by a ceiling in the contract (e.g. travel, subcontracts, consultants, equipment, indirect rates);

- Authorizing the use of overtime;

- Make any commitments or approve any actions that would create any financial obligation on the part of the Government. All contractual agreements, commitments, or modifications shall be made only by the CO.

The period of this appointment shall be from the date of this memorandum until the completion of the contract (including the submission of all required close-out documentation to the CO), unless otherwise revoked or canceled, in writing, by the CO. If the appointment is revoked for any reason before completion of this contract, you shall turn over all contract-related information in your possession, at the time of revocation, to the successor COR or make other dispositions as directed by the CO. You may not transfer this appointment or any authority provided by it to a successor COR.

Any questions regarding your authority under this appointment should be directed to the CO identified below.

[*Insert CO Name*]
OA/NICHD

Attachments: [*List all applicable attachments, e.g. Contracts, Modifications*]

As an indication that you have read, understand and agree to comply with your COR role and responsibilities, please complete this page and return (with a copy of your FAC-COR certificate) to _____ EPN, Room _____ within 7 calendar days of the date of this appointment

A copy of the above document will be provided to the contractor's business representative and principal Investigator to aid them in understanding your role and responsibility as COR to their contract.

DATE:

TO: [*Insert Name*], Contracting Officer

SUBJECT: Designation of COR to:
Contract Number:
Contractor:

The undersigned acknowledges this COR appointment and accepts the duties, responsibilities and limitations described in the appointment memorandum forwarded on [*Insert Date*].

If during the performance of this contract you will be replaced by another COR, you are required to notify the Contracting Officer and provide a request from your Supervisor to assign a new COR to the contract. Verification of completion of the required Federal Acquisition Certification for Contracting Officers' Technical Representative (FAC-COR) certification training is required. If training has not been completed, the date of the scheduled training should be provided.

The Contracting Officer reserves the authority to cancel a COR appointment in accordance with conditions set forth in the DHHS Federal Acquisition certification for Contracting Officer's Technical Representative (FAC-COR) Certification Program.

Acknowledged by:

COR: Typed Name: _____

Signature: _____

Date: _____

Supervisor: Typed Name: _____

Signature: _____

Date: _____

Appendix 8B: Sample Internal Kick-off Checklist

NICHD Internal Kick-Off Checklist

Contracting Officer:

Contract Specialist:

Contracting Officer's Representative:

When? Within a week after signing the contract prior to a formal kick-off

- ☐ Discuss objectives/desired outcomes
- ☐ Review invoice process
  - ☐ Timing
  - ☐ Merlin routing process (from NICHD Workflow System)
  - ☐ Notify CS/CO to resolve invoicing issues
- ☐ Review document access in Merlin
  - ☐ Grant COR access to Merlin
  - ☐ Contract documents
  - ☐ Status of invoicing
- ☐ Discuss reports/deliverables process
  - ☐ Timing
  - ☐ Schedule
  - ☐ Method
- ☐ Discuss risk(s)
- ☐ Discuss upcoming meetings scheduled
- ☐ Review and sign the COR Designation Memo (COR's roles and responsibilities)
- ☐ Discuss roles and responsibilities of all affiliated parties
  - ☐ COR, CS and CO
- ☐ Review the CPARS roles and responsibilities
- ☐ Develop the formal kick-off meeting agenda (reference the Kick-off Meeting Agenda template)
- ☐ Discuss the importance of open communication

Appendix 8C: Sample Kick-off Meeting Agenda Template

Kick-Off Meeting Agenda

Date:

Location:

Title:

Contracting Officer:

Contracting Officer Representative:

Introductions

- Contracts Office
- <INSERT IC> Program Office
- <INSERT CONTRACTOR>
- <INSERT ISSO (if applicable)>
- <INSERT OTHER PERSONNEL>

Topics for Discussion

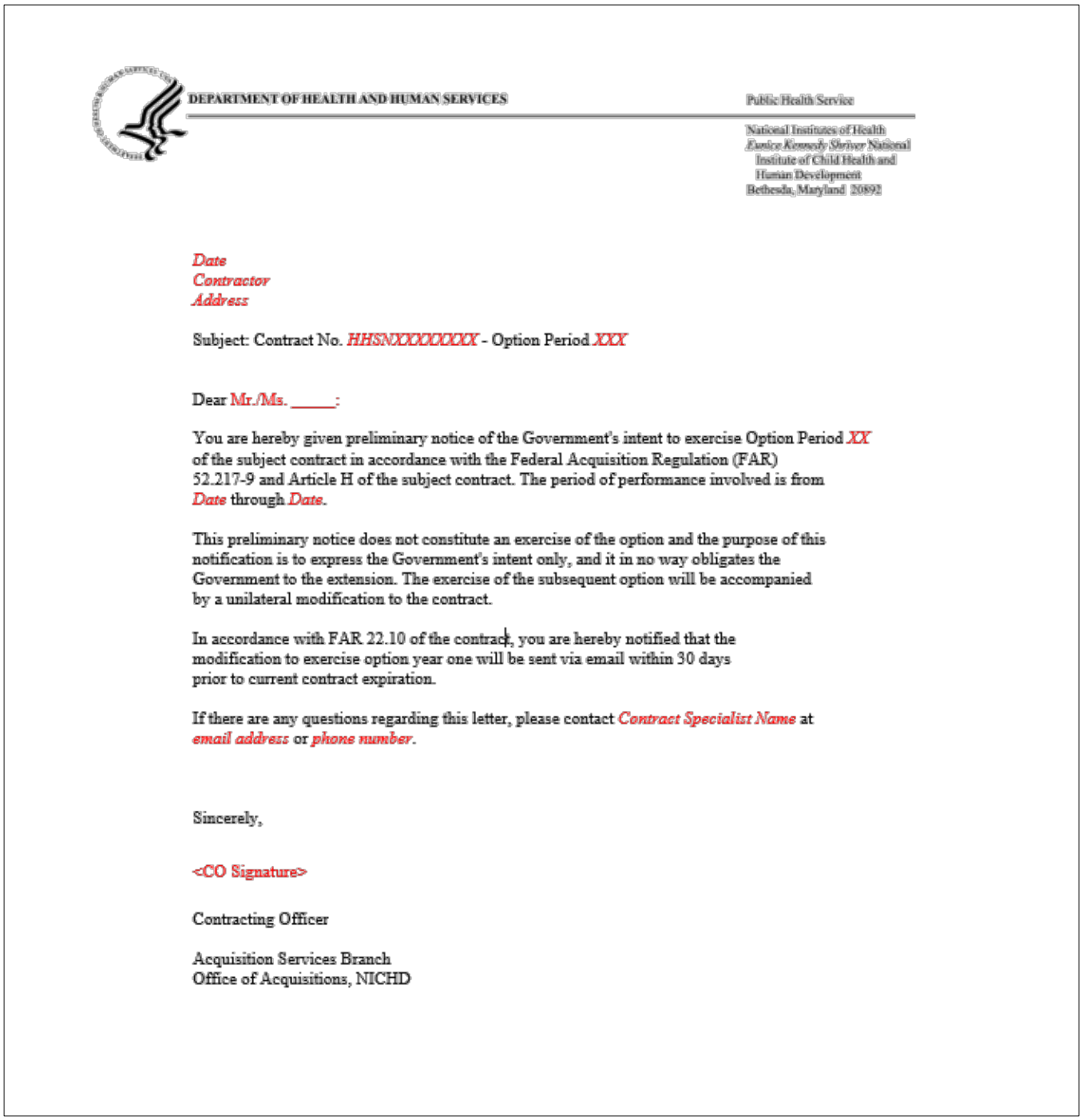
I. **Contracts/Business**
   a. Roles and Responsibilities
   b. Contract Type
   c. Contract Vehicle
   d. Contracting Officer Authorizations
      i. Travel
      ii. Subcontractors
      iii. Equipment
      iv. Conferences
   e. Invoicing
   f. Deliverables/Reporting Requirements
   g. Small Business Subcontracting Plan/eSRS
   h. Key Personnel
   i. Government Property
   j. Rights in Data

II. **Programmatic**
<INSERT TOPICS FROM COR>

III. **Contractor**
<INSERT TOPICS FROM CONTRACTOR>

Appendix 8D: Sample Letter of Intent for Exercising Options

The expected outcome of the Administration Phase is that all contract administration functions are



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

Date
Contractor
Address

Subject: Contract No. *HHSNXXXXXXXXX* - Option Period *XXX*

Dear Mr./Ms. _____:

You are hereby given preliminary notice of the Government's intent to exercise Option Period *XX* of the subject contract in accordance with the Federal Acquisition Regulation (FAR) 52.217-9 and Article H of the subject contract. The period of performance involved is from *Date* through *Date*.

This preliminary notice does not constitute an exercise of the option and the purpose of this notification is to express the Government's intent only, and it in no way obligates the Government to the extension. The exercise of the subsequent option will be accompanied by a unilateral modification to the contract.

In accordance with FAR 22.10 of the contract, you are hereby notified that the modification to exercise option year one will be sent via email within 30 days prior to current contract expiration.

If there are any questions regarding this letter, please contact *Contract Specialist Name* at *email address* or *phone number*.

Sincerely,

<CO Signature>

Contracting Officer

Acquisition Services Branch
Office of Acquisitions, NICHD

National Institutes of Health
Office of Management

Step 9: Closeout

NIH Optimize Acquisitions

1.0 Introduction

The purpose of this document is to outline the steps for the Closeout process for the Offices of Acquisitions at the National Institutes of Health.

2.0 Purpose

The objective of the Closeout step is to identify and resolve any uncompleted obligations or pending liabilities on the part of the Government or the contractor; and to ensure that contract-related decisions and actions have been properly documented, in accordance with FAR 4.804-1.

3.0 Roles and Responsibilities

Contracting Officer's Representative (COR): The COR shall certify receipt of deliverables; review the Final Technical Report; oversee the disposition of property and animals (if applicable); and assist with finalization of the Contractor Performance Assessment Reporting System (CPARS) ratings.

Contract Specialist (CS): The CS serves as the lead on all closeout functions. The CS works with the COR and contractor to ensure that the terms and conditions have been satisfied by both parties. In addition, the CS shall verify that the Final Comprehensive Technical Report has been approved by the COR, and confirm that a copy is in the contract file. The CS is also responsible for supporting the COR and CO for the following activities:

- Identification and determination of the disposition of Government property.
- Certification from the COR related to the performance of the contractor in accordance with the terms and conditions of the contract.
- Confirmation of receipt of the contractor's release of claims.

Contracting Officer (CO): The CO is responsible for overseeing the entire closeout process. The CO must verify that all required administrative actions have been satisfactorily completed.

Contractor: The Contractor is responsible for providing proof of completion of all requirements of the contract; furnishing the Government with all deliverables and the Final Comprehensive Technical Report as stated in the contract; and providing information related to any Government property.

4.0 Expected Outcome

The final contract is complete and includes the CO statement signifying that all required administrative actions have been completed.

5.0 Associated Documents

- COR Certification Form (See Appendix 9A)
- Form 1428 Property Inventory (See Appendix 9B)
- Property Disposition Memo (See Appendix 9C)

Appendix 9A: Sample COR Certification Form

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Acquisitions
Eunice Kennedy Shriver National Institute
of Child Health & Human Development(NICHD)
6710B Rockledge Drive, Room 1124, MSC 7000
Bethesda, MD 20892

Contracting Officer's Representative (COR) Certification of Contract Completion

Date: November 5, 2018

To: «Project_Officer»

From: Kathryn Shippee /

Subject: Request for COR Certification of Contract Completion:

Contract or Task Order number: «Contract_», «Order_»

Project Title: «Title»

Contractor name: «Company»

Contract completion/expiration date: «End_Date»

In order to initiate administrative closeout of the designated contract, please review and complete the certification provided below and return a signed original of this request within 5 business days after receipt. If, for any reason, you are unable to certify satisfactory completion of the contract at this time, please inform me in writing.

CERTIFICATION		
I hereby certify to the best of my knowledge and belief that the above-named Contractor has satisfactorily completed all work requirements of this contract. I further certify that the Contractor is not now in default regarding the furnishing of any deliverables or reports (including final technical report, if required by the contract), disclosures, licenses, equipment, property, data, information, or any other tangible articles required under the terms of the contract.		
COR NAME AND TITLE	**SIGNATURE**	**DATE**

Appendix 9B: Form 1428 Property Inventory

INVENTORY DISPOSAL SCHEDULE (See Reverse for Instructions) (See FAR 52.245 - I (j))	1. TYPE *(Check block(s) where applicable)* ☐ TERMINATION INVENTORY ☐ FINAL SCHEDULE	2. SCHEDULE REFERENCE NUMBER	PAGE NO.	NO. OF PAGES	OMB Control Number: 9000-0075 Expiration Date: 12/31/2018

Paperwork Reduction Act Statement - This information collection meets the requirements of 44 U.S.C. § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget (OMB) control number. The OMB control number for this collection is 9000-0075. We estimate that it will take 2 hours to read the instructions, gather the facts, and answer the questions. Send only comments relating to our time estimate, including suggestions for reducing this burden, or any other aspects of this collection of information to: U.S. General Services Administration, Regulatory Secretariat Division (M1V1CB), 1800 F Street, NW, Washington, DC 20405.

3. PRIME CONTRACT NO.	4. SUBCONTRACTOR/P.O. NO.	5. CONTRACT TYPE	6. TERM DOCKET NUMBER	7. TOTAL LINE ITEMS	8. TOTAL ACQUISITION COST

9a. CAGE CODE	9b. PRIME CONTRACTOR *(Point of Contact)*	10a. CAGE CODE	10b. SUBCONTRACTOR *(Point of Contact)*
9c. STREET ADDRESS		10c. STREET ADDRESS	
9d. CITY, STATE, AND ZIP CODE		10d. CITY, STATE, AND ZIP CODE	

11a. LOCATION OF PROPERTY	11b. POINT OF CONTACT FOR PROPERTY	12. PRODUCT COVERED BY CONTRACT/ORDER

13. ITEM NO.	14. ITEM DESCRIPTION	GOVT. 15. FURNISHED/ CONTRACTOR ACQUIRED	16. DML CODE	17. PROPERTY CLASSIFI-CATION	18. GOVERNMENT PART OR DRAWING NUMBER AND REVISION NUMBER	19. CONDITION CODE	20. QUANTITY	21. UNIT OF MEASURE	22. COST UNIT (a)	22. COST TOTAL (b)	23. CONTRACTOR'S OFFER

24a. SIGNATURE OF CONTRACTOR SUBMITTING SCHEDULE	24b. NAME OF CONTRACTOR SUBMITTING SCHEDULE	24c. TITLE	24d. DATE

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1428 (REV. 1/2016)
Prescribed by GSA-FAR (48 CFR) 53.245(e) and 53.249(b)

INSTRUCTIONS

The Contractor shall submit all schedules to the Plant Clearance Officer.

Manual submissions. Prepare a separate schedule for items in each property classification (block 17) and a separate schedule for scrap. Submit an original and 2 copies of each scrap schedule and continuation sheet (SF 1429). For other schedules, an original and 7 copies are required.

Electronic submissions. Group all items of the same property classification. Submit separate schedules for scrap.

General instructions.

BLOCKS 1, 2 & 4 - Self-explanatory.

BLOCK 3 - PRIME CONTRACT NO. ***(For contract modifications and BOAs).*** If the property applies solely to one contract modification indicate the modification number after the contract number. For task orders and orders under basic ordering agreements, enter the contract number or BOA number followed by the order number under which the property is accountable.

BLOCK 5 - CONTRACT TYPE. Use one of the following codes:

J - Fixed-Price
O - Other
S - Cost-Reimbursement
Y - Time-and-Material
Z - Labor-Hour
9 - Task Order Contracts and Orders under Basic Ordering Agreements (BOAs)

BLOCKS 6 - 8 - Self-explanatory.

BLOCKS 9a and 10a - CAGE CODE. Enter the Commercial and Government Entity code when applicable.

BLOCKS 9b-d, 10b-d, and 11a-13 - Self-explanatory.

BLOCK 14 - ITEM DESCRIPTION. Describe each item in sufficient detail to permit the Government to determine its appropriate disposition. Scrap may be described as a lot including metal content, estimated weight and estimated acquisition cost. For all other property, provide the information required by FAR 52.245 - 1 (f)(1)(iii). List the national stock number (NSN) first. For the following, also provide:

Special tooling and special test equipment. Identify each part number with which the item is used.
Computers, components thereof, peripheral and related equipment. The manufacturer's name, model and serial number, and date manufactured.
Work in process. The estimated percentage of completion.
Precious metals. The metal type and estimated weight.
Hazardous material or property contaminated with hazardous material. The type of hazardous material.
Metals in mill product form. The form, shape, treatments, hardness, temper, specification (commercial or Government), and dimensions (thickness, width, and length).

BLOCK 15 - GOVERNMENT FURNISHED/CONTRACTOR ACQUIRED. Per line item, enter one of the following:

GF - Government furnished
CA - Contractor acquired

BLOCK 16 - DML CODE. ***(Demilitarization code).*** If applicable, enter the code specified in DoD 4160.21-M-1.

BLOCK 17 - PROPERTY CLASSIFICATION. Use one of the following classifications for each line item:

EQ - Equipment
M - Material
STE - Special test equipment
ST - Special tooling

In addition, when applicable, list one of the following sub classifications for each line item below the property classification:

COM - Computers, peripherals, etc.
AAE - Arms, ammunition and explosives
PM - Precious metals
HAZ - Hazardous materials
ME - Metals in mill product form
WIP - Work in process
CL - Classified

BLOCK 18 - Self-Explanatory.

BLOCK 19 - CONDITION CODE. Assign one of the following codes to each item:

Code 1. Property which is in new condition or unused condition and can be used immediately without modifications or repairs.

Code 4. Property which shows some wear, but can be used without significant repair.

Code 7. Property which is unusable in its current condition but can be economically repaired.

Code X. Property which has value in excess of its basic material content, but repair or rehabilitation is impractical and/or uneconomical.

Code S. Property has no value except for its basic material content.

BLOCKS 20 - 22 - Self-explanatory.

BLOCK 23 - CONTRACTOR'S OFFER. The Contractor's offer to purchase the item if it survives screening.

STANDARD FORM 1428 (REV. 1/2016) **BACK**

Appendix 9C: Property Disposition Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Phone: 301-496-4611
Fax: 301-402-3676

National Institutes of Health (NIH)
Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD)
Office of Acquisitions
6710B Rockledge Drive RM 1117B MSC 7000
Bethesda, MD 20892

DATE:

TO: FILE

FROM:
Contracting Officer, NIH, NICHD, OA, CMB

SUBJECT: Disposition of Property
Contractor:
Contract/Task Order No.:
Expiration Date:

THROUGH: _____
Typed Name, Contracting Officer's Representative

__ The Contracting Officer's Representative and the Contracting Officer have determined that there was no Government property provided or acquired under the above referenced contract.

The Contracting Officer's Representative and the Contracting Officer have determined that, on the above referenced contract, the property may be:

__ Donated

__ Abandoned

__ Transferred into another contract (a contract modification is required before transfer).

This determination is due to the age of the property and it would not be cost effective to return it back to NIH.

__ Brought back to the NIH

__ Other, please explain _____

_____
Contracting Officer Signature Date