

A Guide To The

NIH
ACQUISITION
PROCESS



PREFACE

This is a general guide to assist potential contractors not familiar with the National Institutes of Health (NIH) acquisition program. It answers frequently asked questions about how to learn of NIH plans to award a contract and the proposal evaluation process.

Besides providing information on the initiation, award, and administration of contracts sponsored by the components of the NIH, this guide also includes a discussion of the distinctions between acquisition and assistance.

Note that NIH Offices of Acquisition use Simplified Acquisition Procedures for purchases under the threshold of \$100,000 and commercial items up to \$5,000,000. Acquisitions of this type include, but are not limited to purchase orders, record of call orders, and ordering from General Services Administration schedules. This guide does not discuss acquisitions using the Simplified Acquisition Procedures.

The material in this guide is subject to revision by statute, regulation, or through the decision-making processes. Therefore, this guide serves as a general reference and not considered all-inclusive or authoritative. It does not replace the Federal Acquisition Regulation or the terms of any particular contract. Within these limits, we hope that it proves beneficial to the reader.

We expect to revise the guide periodically to meet developing needs. We welcome suggestions for improvement of the NIH acquisition program and hope that all NIH contractors or potential contractors communicate with us. Readers also should note the Office of Acquisition Management and Policy Home Page at <http://oamp.od.nih.gov/>.

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January 2007

PART I

GENERAL INFORMATION ABOUT THE NIH ACQUISITION PROCESS

The NIH is the principle health research component of the Department of Health and Human Services (DHHS). Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. The NIH partly accomplishes this mission by supporting and conducting both basic and applied behavioral and biomedical research in its own facilities. In addition, it supports or acquires scientific investigations and developmental efforts performed by other organizations through acquisition (contracts) and assistance (grants and cooperative agreements).

Apart from its research mission, the NIH also conducts non-Research and Development (R&D) acquisitions to provide general supplies and services, construction, and Information Technology resources.

1. Distinctions between Contracts as Acquisition Instruments, and Grants and Cooperative Agreements as Assistance

There are fundamental distinctions between acquisition and assistance arrangements. A contract is a legal instrument used to reflect a relationship between the Federal Government and the recipient whenever the principle purpose of the transaction is to acquire goods or services for the direct benefit or use of the Government. Generally, the Government states the work to be undertaken or the problem to be solved in Requests for Proposals (RFPs), or Invitations for Bids (IFBs). Respondents compete for a common requirement open to all qualified offerors/bidders. Proposals are evaluated using technical and business evaluation criteria and the process usually involves negotiations to determine the best value for the Government. Bids are awarded to responsible, responsive bidders considering only price and price-related factors.

Unsolicited proposals to perform original, unique, and innovative concepts are an exception to competitive solicitations initiated by the Government and are described in Part II, Section 9.

Grants and cooperative agreements are financial assistance mechanisms that provide money and/or direct assistance to carry out approved activities. The Government awards a grant whenever it does not anticipate substantial programmatic involvement with the recipient during performance. The Government uses a cooperative agreement when it does foresee substantial programmatic involvement with the recipient during performance.

2. The NIH Acquisition Organization

The NIH comprises a number of separate Institutes and Centers (ICs) and carries out its acquisition functions in numerous Offices of Acquisitions (OA). The NIH product and/or supply acquisitions range from basic office, medical, and information technology supplies and equipment to sophisticated state-of-the-art biomedical equipment and systems. The NIH service acquisitions include construction, management consulting, and complex biomedical R&D such as clinical trials. This broad range of acquisitions provides the necessary support for the NIH to carry out its mission. The responsibility for negotiating, awarding and administering these acquisitions lies within the various OA. NIH acquisitions are under the cognizance of the Head of the Contracting Activity (HCA), Director, Office of Acquisition Management and Policy (OAMP). The organization structure is posted on: http://oamp.od.nih.gov/AcquisitionOffices/chief_cos1.asp.

3. The Role of the Contracting Officer

An officially appointed Contracting Officer (CO) is the exclusive agent of the Government and is the only person empowered to execute or modify a contract on behalf of NIH. COs may act through their authorized representatives, known as Contract Specialists, in matters that do not involve the execution of contract instruments.

4. The Role of the Project Officer

The Government appoints a Project Officer (PO) experienced in the scientific and technical disciplines addressed in a particular project to each contract. The PO is responsible for monitoring the technical aspects and assisting the CO in the administration of the contract. The PO has a primary relationship with the Contractor's Program Manager. The PO monitors the contractor's technical progress and assists in the resolution of technical problems encountered during performance.

5. Regulations Governing Contracting

The Federal Acquisition Regulation (FAR) and the Health and Human Services Acquisition Regulation (HHSAR) govern all NIH contracts. The FAR is on the GSA web site <http://www.arnet.gov/far/>. The HHSAR is on the HHS web site <http://www.knownet.hhs.gov/acquisition/hhsar/>.

The FAR contains regulations and prescribed procedures that all Government agencies follow in the solicitation, negotiation, award, and administration of their contracts. The HHSAR implements and supplements the FAR and provides DHHS-wide policies, procedures and guidance.

PART II

THE ACQUISITION PROCESS

1. Methods of Contracting

There are two basic methods of contracting used throughout the Government: negotiation and sealed bidding. The NIH requirements for R&D employ the negotiated method of contracting. Non-R&D contracts use both contracting by negotiation and sealed bidding.

Negotiation includes the receipt of proposals from offerors, allows discussion, and usually affords offerors an opportunity to revise their offers before award of a contract. This method provides the contracting parties maximum flexibility to refine the Statement of Work and agree on anticipated costs of performance.

The Government uses sealed bidding whenever it can describe the required supplies or services in precise terms. An award is made to the responsible bidder whose bid, conforming to the IFB, will be most advantageous to the Government, considering only price and price-related factors included in the IFB.

Sealed bidding procedures are more appropriate for the acquisition of construction and standard commercial goods and services. Negotiation is a more suitable method to procure R&D and other services.

2. Flexibility of NIH Contracts

The NIH terms and conditions for negotiated contracts are flexible enough to meet changing requirements as work progresses. Contracts provide the CO with the means to change the Statements of Work by expansion or reduction of work within the general scope. Cost-reimbursement type contracts are subject to funding adjustments during the life of the agreement.

NIH announces many of its R&D contract programs to the scientific community by stating the research requirements in general terms. By doing so, the Government allows offerors to propose innovative solutions to the technical problems identified.

3. Contract Performance Periods

The duration of a contract will vary depending on the requirement, from days or months for some non-R&D contracts (for example, supplies), to several years for complex R&D contracts.

For some multi-year contracts, NIH may use options. The Government negotiates the amounts for all potential years of a contract before award, but only funds the first year. The contract includes all succeeding years as options that the Government may exercise unilaterally.

4. **Competition for Contracts**

The NIH competitively solicits proposals and bids to the maximum practicable extent. Depending on the nature of the requirement, the NIH encourages competition among qualified educational institutions, nonprofit and commercial organizations, which include Small, Small Disadvantaged, Women-owned, Veteran, Service-Disabled, and HUBZone business firms.

5. **Requests for Proposals and Invitations for Bids**

Solicitations contain all information necessary for offerors or bidders to prepare proposals or bids and where required, follow the Uniform Contract Format established by the FAR. Through various means, the Government widely publicizes the availability of solicitations.

Generally, a solicitation provides the: (1) statement of work; (2) performance or delivery schedule; (3) Government-furnished property, if any; (4) contract clauses to be included in the award; and (5) criteria that the Government will use to evaluate the proposals. An RFP also includes instructions to prospective offerors to prepare the technical and cost portions of their proposals.

Solicitations always specify the required date and location for submission of offers or bids. The NIH may consider late proposals or late modifications to proposals if: 1) receipt was delayed due to one of the regulatory exemptions stated in FAR; or 2) all the requisite conditions exist to use the alternate late proposal procedure authorized by HHSAR.

Negotiated statements of work presented in the solicitations usually are flexible enough to give offerors reasonable discretion to provide their own approaches to the contract objectives, but specific enough to ensure that offerors are competing on a common basis. The technical evaluation criteria included in the RFP provide a uniform standard to evaluate the differing approaches to the requirement.

6. **Publicizing Contract Requirements**

Federal Business Opportunities (FedBizOpps) is the single point of entry for all Government acquisitions exceeding \$25,000 and the principle source to learn of planned NIH contracts. The NIH seeks competition in its acquisition programs to the greatest extent possible. Noncompetitive contracts are awarded on an exception basis only. Announcing competitive and noncompetitive solicitations in the *FedBizOpps* provides a wide distribution of the NIH requirements to interested parties.

Besides *FedBizOpps*, the NIH also may use the *NIH Guide for Grants and Contracts (Guide)* for its R&D requirements. It contains policy guidance and administrative information about the NIH programs as well as the RFP announcements.

FedBizOpps maintains an e-mail notification service for presolicitation, solicitation, and postaward notices. Registration is available through its web site <http://www.FedBizOpps.gov>. Send requests to receive the *Guide* to <http://grants.nih.gov/grants/guide/index.html>.

NIH maintains a Home Page as a third method of publicizing available RFPs located at <http://ocm.od.nih.gov/contracts/rfps/MAINPAGE.HTM>.

7. Evaluation of Proposals

NIH evaluates proposals received in response to an RFP from a technical standpoint, including the offerors' past performance on similar projects, and from a business standpoint. The RFP specifies the relative importance of the technical aspects of the proposal versus the cost or price, past performance and socioeconomic program participation.

a. Technical Evaluation of Proposals

Persons who have expertise in the scientific field evaluate proposals professionally and objectively. For R&D and nonR&D requirements, one or more panels in the scientific disciplines perform the technical evaluation. At least three-fourths of the members of the peer review group are nonfederal employees for R&D requirements. For nonR&D requirements, persons within the Federal Government who have appropriate expertise may serve on a committee to evaluate proposals. The technical evaluation criteria published in the RFP are the sole basis of the proposal evaluation. Proposals receive either an acceptable or unacceptable rating.

b. Cost and Price Analysis of Proposals

Technically acceptable proposals also undergo a business evaluation. Cost analysis is the review of the individual cost elements and proposed profit, if any, by an evaluation of the offerors' cost or pricing information and judgmental factors. Government personnel verify and evaluate each cost element based on audit and technical analysis.

Price analysis is the process of examining and evaluating a proposed price without evaluating its separate cost elements and proposed profit. Price analysis entails: (1) comparison of proposed prices received in response to the solicitation; (2) comparison of prior proposed prices and contract prices with current proposed prices for the same or similar items; (3) application of rough yardsticks to highlight significant inconsistencies that warrant additional pricing inquiry; (4) comparison with competitive published price lists; (5) published market prices of commodities; (6) similar indexes and discount or rebate arrangements; and (7) comparison of proposed prices with the independent Government cost estimate. The CO always uses price analysis with negotiated fixed-price contracts and when adequate price competition, as defined in FAR exists to determine price reasonableness.

c. Competitive Range and Discussions

After the technical and business evaluation, the CO establishes a competitive range if discussions are planned. The competitive range identifies those offerors with whom NIH will conduct negotiations, and is composed of the most highly rated, technically acceptable proposals unless the range is further reduced for efficiency. However, the solicitation may state that the Government reserves the right to award without discussions. Therefore, the offerors' initial proposals should contain their best terms from a technical and cost standpoint.

Either written or oral discussions will reveal to each offeror in the competitive range the ambiguities, uncertainties, or deficiencies identified in the evaluation of its proposal. Discussions include all questions affecting technical considerations, cost elements, and administrative matters. Offerors have an opportunity to improve or revise their proposal in a Final Proposal Revision (FPR). The FPR is the basis for the award to the offeror considered most advantageous to the Government.

d. Notifications to Unsuccessful Offerors and Award Announcements

The CO notifies each unsuccessful offeror at the earliest practicable time that its proposal is no longer under award consideration. The *FedBizOpps* publishes award notices for actions exceeding \$25,000.

Upon written request, the CO conducts debriefings for unsuccessful offerors to provide the basis for the contract award. Debriefing information also includes: the Government's evaluation of the significant weaknesses or deficiencies in the offeror's proposal; the overall evaluated cost or price and technical rating of the successful offeror and the debriefed offeror; the overall ranking of all offerors; a summary of the rationale for award; for acquisitions of commercial end items, the make and model of the item to be delivered by the successful offer; and reasonable responses to relevant questions on the agency's compliance with source selection procedures contained in the solicitation and acquisition regulations.

8. Sealed Bid Procedures

The following conditions must be present to use sealed bidding: (1) time permits the solicitation, submission, and evaluation of bids; (2) award will be based on price and other price-related factors; (3) discussions with the responding bidders are not necessary; and (4) there is a reasonable expectation of receiving more than one sealed bid.

Preparation of an Invitation for Bid (IFB) is the next step. It describes the requirements of the Government clearly and completely. The IFB includes all documents necessary to prepare a bid.

The next step is publicizing the IFB. IFBs usually are publicized in the *FedBizOpps*, through distribution to prospective bidders and posting in public places. Publicizing occurs in sufficient time before public opening of bids to enable prospective bidders to prepare and submit bids.

The Government keeps bids unopened and secured until the time of public opening. Bidders must submit sealed bids to be received at the location and by the time stated in the solicitation. A late bid is not considered for award, unless one of the exemptions stated in FAR Part 14 applies.

The Bid Opening Officer publicly opens the bids, reads the bids aloud to those present, and records the bids. Original bids are kept by the Government official but can be viewed by the public under Government supervision.

The CO evaluates the bids for responsiveness, responsibility and reasonableness of price.

The Government determines responsiveness based on the timely submission of bids prepared in accordance with the instructions outlined in the IFB.

A bidder is determined responsible when it: (1) has adequate financial resources to perform the requirement or the ability to obtain them; (2) is able to comply with the required delivery or performance schedule, considering all existing commercial and governmental business commitments; (3) has a satisfactory performance record; (4) has a satisfactory record of integrity and business ethics; (5) has the necessary organization, experience accounting and operation controls, and technical skills, or the ability to obtain them; (6) has the necessary production, construction, and technical equipment and facilities or the ability to obtain them; and (7) is otherwise qualified and eligible to receive an award under applicable laws and regulations.

The CO awards the contract after determining reasonableness of price and the most advantageous bid to the Government.

9. Unsolicited Proposals

In addition to contracts that NIH plans and develops, unsolicited proposals may result in awards. An unsolicited proposal is a written offer for a new or innovative idea that the Government agency may find meritorious and useful to advance its mission. A valid unsolicited proposal must be innovative and unique; and independently originated and developed by the offeror. The offeror must prepare it without Government involvement and include sufficient detail to permit a determination that Government funding could benefit the NIH mission. Based on these criteria, three or more experts (the majority of whom are not required to make recommendations on the action as part of their official duties) perform an evaluation of the proposal.

An unsolicited proposal may be the basis for a Government competitive solicitation, if the RFP in no way reveals the original ideas or approaches of the originator. For example, an unsolicited proposal may represent one possible approach to a common problem. If there are other possible approaches, it may be in the best interest of the Government to issue a competitive solicitation. When competition is appropriate, the Government will invite the originator to participate under the competitive RFP.

10. Small Business Program

The Small Business Act of 1958, as amended, and the Small Business Investment Act of 1958 reflects the declared policy of the Congress that small business concerns should receive a fair proportion of the contracts and purchases of the Federal Government. It is the policy of the Federal Government to provide maximum practicable opportunities in its prime contracts and subcontracts to small business concerns.

The DHHS and all of its Operating Divisions implement this Federal socioeconomic policy through an established Small and Small/Disadvantaged Business Utilization Program.

The Small Business Administration (SBA) has authorized NIH to enter directly into contracts with eligible and certified small and disadvantaged businesses. Acquisitions (contracts and purchases) are offered to the 8(a) Program based on recommendations by agency COs, POs, Small Business Specialists, or as a result of requests from the SBA for firms in their portfolio.

The small business set-aside is a mechanism by which the Government reserves acquisitions for the exclusive participation of small business concerns. POs and COs may initiate small business set-asides or the Small Business Specialist may recommend a set-aside when there is a reasonable expectation of receiving at least two offers from responsible concerns capable of providing the products at a fair market price.

Public Law requires that every contractor awarded contracts exceeding the simplified acquisition threshold must agree to subcontract with Small, Small Disadvantaged, Women, HUBZone, Veteran-owned, and Service-Disabled Veteran-Owned businesses to the maximum extent practicable. Each contract with "other than a small business" anticipating subcontracting opportunities expected to exceed \$550,000 (or \$1,000,000 for construction) must have an approved subcontracting plan prior to award. The goals established for Small, Small Disadvantaged, Women, HUBZone, Veteran-owned, and Service-Disabled Veteran-Owned businesses must reflect a "good faith" effort to provide maximum practicable subcontract opportunities.

11. The Small Business Innovation Research (SBIR) Program

Public Law 106-554, the Small Business Reauthorization Act of 2000, requires the DHHS and certain other Federal agencies reserve a specified amount of their overall extramural R&D budgets for the SBIR Program. The purpose of this legislation is to stimulate technological innovation, encourage small business participation in Federal R&D, and increase small business commercialization of technological innovations derived from federally funded R&D.

For R&D efforts, a "small business" is a concern organized for profit, has its principle place of business in the United States, is not dominant in its field, and has no more than 500 employees. The Government selects SBIR projects to fulfill broad program directives and solve priority technological problems and produce technology or products with commercial applications.

Because these projects usually are highly scientific in nature, a panel of scientists reviews SBIR proposals. At least three-fourths of the panel must be non-Federal employees and expert in the scientific field identified with the SBIR topic area.

The SBA maintains a web site that announces SBIR solicitations across all participating Government agencies at <http://www.sba.gov/sbir/indexprograms-otaagency.html> . See additional information on the NIH SBIR Program at <http://grants.nih.gov/grants/funding/sbir.htm#sbir/>.

12. NIH Acquisition Policies

Within the limits of statutes and Federal regulations, there are opportunities for innovation to improve acquisition procedures and relations between the contracting parties. We welcome views from the community at large on ways of enhancing the quality and effectiveness of our acquisition programs and procedures. Direct specific questions regarding the acquisition programs to the offices listed in the solicitations and contracts.