NIH Policy Manual

6315-1 - Initiation, Review, Evaluation, and Award of Research & Development (R&D) Contracts

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Transmittal Notice

1. **Explanation of Material Transmitted:** This chapter, pursuant to HHSAR Subpart 304.71 and other authority, implements provisions of the Public Health Service Act as amended by the Health Research Extension Act of 1985, Federal and HHS acquisition regulations, and related policies and regulations on the initiation, review, evaluation, and award of NIH R&D contracts.
2. **Filing Instructions:**

   Remove: NIH Manual Chapter 6315-1, dated April 23, 1991.
   Insert: NIH Manual Chapter 6315-1, dated October 18, 2004.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Manual System, contact the Office of Management Assessment, OM on (301)496-2832.
- Online information, enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose

This chapter presents policies and procedures for the initiation, review, evaluation, negotiation, and award of NIH biomedical and behavioral Research and Development (R&D) contract projects. It applies to all contract projects for the conduct of R&D and the direct support of the conduct of R&D, including innovative testing, research, demonstration, and related efforts. The term R&D includes research, development, demonstration and R&D support. See Section H for a full definition. This chapter supplements the Health and Human Services Acquisition Regulation (HHSAR Part 315).

This chapter does not apply to contracts for purposes incidentally related to R&D, that is, non-R&D, such as:

- The routine purchase of commercial items sold, leased, or licensed (or offered for sale, lease or license) to the general public with published price lists, etc., "off-the-shelf" laboratory or general equipment, materials, supplies, animals, or routine services for R&D projects;
- The conduct of program evaluations, public or technical information services or clearinghouses, scientific conference or logistics support, or other services neither directly performing nor directly supporting R&D; nor
- The performance of minor enhancements to existing equipment or systems.

This chapter is established pursuant to HHSAR Subpart 304.71 and other authority requiring the Head of the Contracting Activity to establish review and approval procedures for proposed contract actions, designate acquisition officials, and determine the criterion (or criteria) to be used in determining which contracts are to be reviewed. This chapter should not be read to abrogate any Contracting Officer authority or responsibilities as described in the Federal Acquisition Regulation (FAR), including at FAR Subpart 1.6 and FAR Subpart 15.5.

B. Background

Thorough, competent, scientific, technical and business reviews of biomedical and behavioral R&D contract projects constitute essential features of the contracting process. They serve to:

- promote best selection of projects to accomplish high priority NIH program needs;
- engender competition among qualified offerors;
- establish technical ranking of proposals;
- specify technical and business issues, for example, strengths and weaknesses, to enable meaningful discussions; and
- promote submission of optimal Final Proposal Revisions.

All these functions help decision-making for selection of projects and sources that offer the best value to the Government. They contribute toward fulfilling identified NIH requirements for R&D contracts.

C. Policy

NIH requires competent, objective, and expeditious evaluation of biomedical and behavioral R&D contracts, conducted by qualified reviewers. Procedures implementing this policy aim to ensure optimal selection of contracts, based on established program priorities and needs, maximal opportunities for effective competition, and awards to sources most likely to achieve NIH objectives at a fair and reasonable cost. All biomedical and behavioral R&D contracts require peer review and approval of both project concepts and proposals before contract award, regardless of whether they originate from extramural or intramural program requirements.

Peer review of R&D contract concepts evaluates the basic purpose, scope, and objectives of the projects and establishes relevance, priority, and need to accomplish NIH objectives.

Peer review of R&D contract proposals provides objective evaluation of technical aspects and acceptability or unacceptability of specific proposals based on the technical evaluation criteria. Further it helps to achieve program goals by identifying the best technically qualified offerors.

The review of R&D technical proposals must be conducted in a manner consistent with the standards of quality for technical and scientific peer review (see 42 CFR 52h).

Subsequent staff reviews, including Source Selection Panels (SSP), and negotiations with offerors aim to select contractors most capable of accomplishing stated requirements to the best possible advantage to the NIH.

Responsible NIH staff must ensure that reviews provide for the most competent advice to guide decisions on selection and award of contracts. Throughout the process, staff must avoid actual or apparent conflicts of interest, maintain confidentiality of information, and comply with procurement integrity requirements.

Contract actions are subject to Protests as defined in FAR Part 33. The CO shall consider all protests and seek legal advice in conjunction with the NIH Protest Control Officer, whether protests are submitted before or after award and whether filed directly with the CO or the Government Accountability Office.

Evaluation of business proposals determines the reasonableness of cost elements and business management capabilities of offerors to perform the required work.

The Appendix shows the steps in the process from project development through contract award.

D. Responsibilities

1. The Deputy Director for Extramural Research, NIH, establishes NIH policies and procedures for scientific review and evaluation of R&D projects, and determines the adequacy of procedures implementing those principles.
2. The Head of the Contracting Activity, Director, Office of Acquisition Management and Policy, establishes NIH policies and procedures for business reviews, evaluations and awards for R&D contracts under requirements established in the FAR and HHSAR and determines the adequacy of procedures implementing those principles.
3. Institute/Center (IC) Directors ensure adherence within their organizations to established NIH policies, and maintain adequate communication between program, contracting, and review staffs.
4. Senior IC program, review, and contracting officials oversee contracting activities and are responsible for ensuring the adequacy of scientific peer review, program, and

business review.

5. Contracting Officers (COs) collaborate with Project Officers (POs) to develop Acquisition Plans/Request for Contract (AP/RFC) documents for R&D contracts based on scientific needs and market research appropriate to the circumstances. They monitor and assist technical evaluations to ensure compliance with acquisition regulations. Also, they conduct administrative/business reviews of contract proposals. COs establish the competitive range, conduct cost analyses and negotiations, select and award R&D contracts based on established requirements and results of peer reviews.
6. POs collaborate with COs to develop AP/RFC documents and provide program information for R&D project concept and proposal reviews. They serve as a scientific resource and summarize the background and objectives of Requests for Proposals (RFPs) to ensure that the Scientific Review Group (SRG)understands the intent of the RFP. Also, they advise COs regarding technical aspects of competitive range discussions and final negotiations. See DHHS Project Officers' Contracting Handbook. http://www.knownet.hhs.gov/acquisition/POHandbookSTD.doc
7. Scientific Review Administrators (SRAs) establish and supervise equitable scientific reviews and evaluations for R&D contract proposals. They ensure that SRG members have no real or apparent conflicts of interest precluding their participation in proposal reviews in a given competition, unless a waiver is obtained under 42 CFR 52(h) to allow a member's participation under defined circumstances. They ensure reviewers sign and submit Conflict of Interest, Confidentiality and Non-Disclosure of Information Certifications. SRAs interact with POs and COs as necessary to understand the review requirements of the acquisition, including providing advice on evaluation criteria during AP/RFC development. They document the SRG reviews to the CO and PO. (See NIH Manual Chapter 1805, Use of Advisors in Program and Project Review and Management).
http://www1.od.nih.gov/oma/manualchapters/management/1805/

E. Procedures: Acquisition Through Full and Open Competition

1. Presolicitation Procedures

Presolicitation R&D contracting procedures include interactions by program, contracting, and review staffs to:

- develop the project concept;
- obtain scientific peer review of the concept to establish relevance, priority, and need;
- develop the AP/RFC as a planning document; and
- prepare a Request for Proposal (RFP), describing the Government's needs, soliciting offers based on specific requirements, often seeking innovative and original approaches to accomplish the tasks described in the RFP.

a. Project Concept

NIH Scientific Peer Review regulations require that ICs obtain peer review of each R&D contract project concept before issuing a Request for Proposals for biomedical and behavioral research (42 CFR 52h.10). The concept identifies the basic purpose, scope and objectives of the project.

Timely project concept reviews are required for all R&D contract projects. Usually program staffs develop R&D project concepts based on prior discussions with advisory groups and other interactions with the scientific community. The concepts are evaluated according to IC procedures before beginning the acquisition process. If IC staff cannot easily judge whether a given contract project belongs in the R&D category, it should choose the course of peer review to ensure a broad base of expert advice and justification for contract award.

Before issuing an RFP, the CO ensures that a peer review group/SRG (e.g. Advisory Council or Board, Board of Scientific Counselors, Program Advisory Group (PAG), Special Emphasis Panel) approved the project concept under requirements of 42 CFR 52h. Under certain circumstances, the IC Director or designee may defer or waive project concept review. See a.(2) and (3) below).

Title 42 CFR 52h and NIH Manual Chapter 1805 restrict awarding IC staff from functioning as members or SRAs of SRGs or PAGs on contract projects or proposals for which they have other selection, award, or administration responsibilities. The PO may not serve as SRA (or PAG executive secretary) or prepare the summary minutes for R&D concept reviews.

(1) Recommendations

PAG/SRG recommendations must address concepts for specific projects rather than broad program activities. When PAGs review project concepts, SRA or program staff must make it clear that the IC seeks their advice on the project(s) anticipated for funding as R&D contracts.

(2) Deferral from Presolicitation Concept Review

The IC Director or designee may defer the presolicitation peer review of a project concept if he or she determines that the accomplishment of essential program objectives would otherwise be placed in jeopardy and any further delay clearly would not be in the best interest of the Government. When the Director or designee defers presolicitation concept review, he or she shall document the basis for that determination. The RFP shall state that a peer review group has not reviewed the project concept and must do so before proposal review to allow award.

NIH prefers that different peer review groups review project concepts and

proposals.

(3) Exclusions from Presolicitation Concept Review

The IC Director or designee may determine and document to the CO that project concept review is not needed when:

(a) the solicitation is to recompete or extend a project that is within the scope of a current project that has been peer reviewed;

(b) Congress authorizes or mandates the IC to accomplish specific contract projects. It is considered sufficient authority to pursue those activities without additional advisory input;

(c) projects are not for the actual conduct or direct support of R&D activities. Examples include: scientific conferences to exchange information on R&D fields or results; or purchases of commercially available supplies, services, animals; and

(d) the solicitation is for an evaluation project that assesses productivity, impact, or quality of NIH programs, and the NIH Technical Merit Review Committee (TMRC) has already reviewed the project. Additional information on the TMRC and the use of 1% Set-Aside funds can be found at http://www1.od.nih.gov/osp/de/.

(4) Project Concept Reviews

ICs may review project concepts by various appropriate means, including chartered program and policy advisory committees and SRGs, or seminars, conferences and workshops for specific program areas, whenever these meet the definition and composition requirements of "peer review group" in 42 CFR 52h. Also see NIH Manual Chapter 1805. Staff responsible for these reviews shall make clear to participating advisors that the IC seeks their advice with respect to the anticipated project(s). ICs may conduct concept reviews by mail or electronic means. In all cases, ICs shall present a specific concept for approval with corresponding background and rationale (estimated total costs may be included), and include the vote for approval or disapproval in formal concept review minutes.

Concept review groups shall consider features of the purpose, scope and objectives which are specific to each R&D project, including:

- scientific, technical, or program significance of the goals of the proposed R&D activity;
- availability of the technology and other resources necessary to achieve

the required goals;
- extent to which identified, practical scientific or clinical uses exist for the anticipated results; and
- adequacy of inclusion of women, minorities and children in clinical research, if applicable.

(5) Meetings

Insofar as possible, attendance at concept review meetings may include contracting and review staff appropriate to the projects under discussion, as well as program staff responsible for program presentations and subsequent project management.

Concept review meetings are generally open to the public under provisions of the Federal Advisory Committee Act, as amended (5 USC, Appendix 2). Persons who attend or participate in meetings, and their affiliated institutions, are eligible to receive contract awards resulting from subsequent RFPs, unless other factors contravene.

ICs may disclose information about agency mission needs and future requirements at any time. After release of the solicitation, the CO must be the focal point of any exchange with potential offerors. When specific information about a proposed acquisition that would be necessary for the preparation of proposals is disclosed to one or more potential offerors, that information must be made available to the public as soon as practicable, but no later than the next general release of information, to avoid creating an unfair competitive advantage. See FAR 15.201(f).

(6) Documentation

IC staff should document concept reviews with summaries of staff presentations and peer review group opinions and recommendations for approval. These summaries must become part of the official contract file.

b. Exchange with Industry

NIH encourages exchanges of information among all interested parties, from the earliest identification of a requirement through receipt of proposals. Any exchange of information must be consistent with procurement integrity requirements (see FAR 3.104). An early exchange of information among industry and the program manager, contracting officer, and other participants in the acquisition process can identify and resolve concerns regarding the acquisition strategy, including:

- proposed contract type, terms and conditions, and acquisition planning schedules;
- the feasibility of the proposal instructions and evaluation criteria; including the approach for assessing past performance information;
- the availability of reference documents; and
- any other industry concerns or questions.

Some techniques to promote early exchange of information include: industry or small business conferences; presolicitation notices; draft RFPs; site visits, etc. For additional details see FAR 15.201.

c. Acquisition Plan/Request for Contract (AP/RFC)

This document constitutes approval and authorization of an acquisition, allows issuance of an RFP, and future obligation of funds, according to IC procedures.

Program staff shall initiate the preparation of the AP/RFC, which is the joint responsibility of program and contracting staff. As needed, review staff may be called upon for assistance. The AP/RFC contains all information needed to prepare the RFP. Therefore, the AP/RFC and RFP must be clear, complete, and likely to engender effective competition. In particular, the Statement of Work (or Statement of Objectives); technical evaluation criteria; and RFP Section L - Instructions, Conditions, and Notices to Offerors, must reflect those considerations.

Whenever possible, performance-based contracting methods should be used for acquisitions including R&D. See FAR Subpart 37.6, and the Seven Steps to Performance-Based Services Acquisition: https://www.acquisition.gov/comp/seven_steps/library/sevensteps_execversion.pdf.

An AP/RFC contains documentation of clearances and a schedule of milestones for solicitation, post solicitation and award phases. See the Appendix to this document and the Acquisition Process Mapping at http://acq-map.oamp.od.nih.gov for additional details. Information elements in the AP/RFC are detailed in FAR 7.105 and HHSAR 307.1. HHSAR 307.71 combined these requirements into a single format for use by contracting activities.

IC components responsible for review of proposals should assist in developing technical evaluation criteria to identify ambiguities, inconsistencies or appropriateness of the criteria in relation to the statement of work.

Final presolicitation steps include: approval of the RFC, Small Business clearance, availability notice in FedBizOpps and other selected sites; preparation and review of the RFP. After release of the solicitation, the CO must be the focal

point of any exchange with potential offerors.

The Division of Acquisition Policy and Evaluation, Office of Acquisition Management and Policy, may conduct presolicitation reviews prior to, or concurrent with, issuance of an RFP. See NIH Manual Chapter 6304.71 for more details.

The program office's preparation of the RFC, submission to the contracting office and its approval completes the presolicitation phase of the acquisition planning process and commences the solicitation phase. The RFC is the formal document that initiates the preparation of the solicitation by the contracting office and sets the acquisition process in motion. It is the result of the planning by the PO and CO and contains much of the pertinent information necessary for the development of a sound, comprehensive solicitation.

d. Special Considerations

Certain projects require special clearances or approvals before the CO may execute the contract. POs and COs should consider such areas sufficiently early in the acquisition process so that they are identified as requirements in the RFP and addressed in the roposal and negotiations so that they do not delay awards. Some clearances include:

(1) Animal Welfare

Generally, ICs will not award contracts involving the care and use of vertebrate animals until after appropriate clearance consistent with NIH Manual Chapter 6380-2/54206. These requirements apply if any animals are used in the contract, even if it is not an R&D project. See additional information at: http://grants1.nih.gov/grants/olaw/olaw.htm

(2) Biohazard Security

To help ensure the protection of the life and health of all persons, and to help prevent damage to property, Contractors must comply with all Federal, State and local laws and regulations applicable to the contract work. The Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels implement and/or enforce these laws.

The CO must include HHSAR Clause 352-223.70, Safety and Health, in all awards involving toxic substances, hazardous materials, or operations.

(3) Biomedical Research Resources

NIH designed the present policy to assist funding recipients determine: 1) reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools), and 2) restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding agreements.
http://ott.od.nih.gov/NewPages/64FR72090.pdf

(4) Data, Data Rights, Patents, Copyrights

Whenever contractors will use, develop or enhance data, in any form, NIH and the contractor must consider how to use, maintain, disclose, dispose, and protect it for future use. In addition to data subject to the Privacy Act, COs must carefully consider when the contractor is to develop or enhance software and other special data such as Audiovisual and Media materials. The PO and CO must explore how to license this data, and whether special permissions and copyright needs exist to protect the Government's rights to this data. The NIH Office of Technology Transfer can provide guidance in this area and should be contacted when special data needs arise in the contract requirement.

(5) Data Security

NIH Chief Information Officer establishes data security policy in accordance with OMB Circular A-130. See http://irm.cit.nih.gov/security/secplantemp.doc. The PO and IC Information Systems Security Officer must determine if the contract will be subject to the requirements of the DHHS Automated Information Systems Security Plan.

(6) Data Sharing

NIH developed a statement on sharing research data that supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. The RFP and contract will require Offerors to include a plan for data sharing or to state why data sharing is not possible. This requirement applies to all proposals with direct costs greater than $500,000 in any single year. For more information, see the Web site below:
http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

(7) Electronic And Information Technology Accessibility Standards

Section 508 of the Rehabilitation Act of 1973 applies when Federal

departments or agencies develop, procure, maintain or use electronic and information technology (EIT). It requires Federal agencies to ensure their EIT allows Federal employees with disabilities to have access to, and use of, information and data comparable to the access and use by Federal employees without disabilities. Section 508 also requires members of the public with disabilities, who are seeking information or services from a Federal agency, to have access to, and use of, information and data comparable to that provided to members of the public without disabilities. See The Section 508 Standards Page, 36 CFR Part 1194 and FAR Subpart 39.2.

(8) Foreign contracts

All foreign contracts and subcontracts require prior clearance in accordance with procedures in NIH Manual Chapter 6325-1. The need for both NIH and State Department clearances suggests that COs allow more time for such awards.

(9) Health Insurance Portability andAccountability Act (HIPAA)

The privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), apply to health information created or maintained by health care providers who engage in certain electronic transactions, health plans, and health care clearinghouses. Offerors need to consider the requirements for compliance. See http://dhhs.gov/ocr/hipaa.

(10) Human Subjects

Contracts involving human subjects must meet the requirements of 45 CFR 46 and NIH Manual Chapter 6380-1. The NIH Grants Policy Statement (http://grants1.nih.gov/grants/policy/nihgps_2001/part_iia_2.htm), while mainly a grant tool, contains all of the current NIH policies concerning human subject research. Specific requirements are included in the RFP. See the NCI RFP Workform for a complete listing of possible requirements http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf. Note that these requirements encompass many projects besides clinical trials, and it is essential to determine if specific projects fall within established requirements.

(a) Protection of Human Subjects

See NIH Manual Chapter 6380-1, Contracts Involving Human Subjects.

(b) Inclusion of Women and Minorities in Clinical Studies.

NIH policy is that offerors and contractors for clinical research projects

include women and minorities in study populations so research findings can benefit all persons at risk of the disease, disorder, or condition under study. RFPs must identify when the policy is relevant. If the offeror does not include women/minorities in its proposed study population, or proposes a representation of women and minorities less than that anticipated by the objectives expressed in the Statement of Work, they must provide a specific rationale for this exclusion or under representation. Reviewers will evaluate this rationale during the technical peer review of proposals for its appropriateness in terms of the requirements of the solicitation. Also see: http://grants.nih.gov/grants/funding/women_min/women_min.htm

(c) Inclusion of Children Policy.

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are scientific and ethical reasons not to include them. If offerors exclude children from research proposals, they must present an acceptable justification for the exclusion. Proposals also must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. For further specific requirements on inclusion of children, see the Web site below: http://odoerdb2.od.nih.gov/oer/policies/children.htm

(d) Data and Safety Monitoring Plan

A plan for data and safety monitoring is required as part of the proposal for all NIH supported clinical trials. After award, the contractor must monitor on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Multi-site clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB) based on the risk involved. The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time of protocol development and must be in place before the trial begins. It requires the approval of the Contractor's Institutional Review Board and the Government.

The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered. Also see "Further Guidance on a Data and Safety Monitoring Plan for Phase I and Phase II Trials" http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html and "Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Supported Multicenter Clinical Trials"http://grants2.nih.gov/grants/guide/notice-files/not99-107.html.

(e) Human Subjects Protection Education Plan

NIH policy requires education on the protection of human subject participants for all key personnel receiving NIH contract awards for research involving human subjects. Under this policy, key personnel include all individuals working under a contract who are responsible for the design and/or conduct of the research. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, see the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following Web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

(11) OMB Clearance/Paperwork Reduction Act

The collection of survey or other information from ten or more respondents requires Office of Management and Budget (OMB) review and approval, consistent with NIH Manual 1825. (Also see HHSAR 307.7105.) However, when the respondents are individuals under treatment or clinical examination in connection with research on or prevention of a clinical disorder, or the interpretation of biological analyses or other specimens, or the identification or classification of those specimens, proposed projects may qualify for clinical exemption. The projects are to be submitted to the NIH Clinical Exemption Review Committee for determination of clinical exemption.

(12) Privacy Act

Whenever the CO determines that the Privacy Act applies to a given contract, current systems of records must be reviewed and, if necessary, a new one established and cleared in accordance with FAR Part 24 and HHSAR Part 324.

(13) Recombinant DNA

Any contract using recombinant DNA technology requires prior clearance under provisions of Guidelines for Research Involving Recombinant DNA Molecules. See the NIH Guide Notice at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html. The NIH Guidelines can be viewed on line at:http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

(14) Stem Cells

In order to facilitate research using human embryonic stem cells, the NIH created a Human Embryonic Stem Cell Registry that lists the human embryonic stem cell lines – at varying stages of development – that meet the eligibility criteria. Only the entities that have developed stem cell lines that meet the criteria are eligible for federal funding. For further information see: http://stemcells.nih.gov/index.asp.

e. Request for Proposals

An RFP is the Government's official solicitation document. It communicates to prospective contractors what the Government needs to buy, and invites the submission of proposals. The purpose of the RFP is to convey all the information that prospective offerors need to prepare a proposal. The RFP includes the:

(1) Statement of Work (SOW)/Statement of Objectives (SOO)

The RFP SOW/SOO includes specifics of the project from the AP/RFC that will enable offerors to respond in an appropriate and competitive manner to the RFP. The SOW/SOO should specify the desired results, functions, or end items without telling the offeror what has to be done to accomplish those results unless the method of performance is critical or required for the successful performance of the contract. The SOW must be clear, concise and completely define the responsibilities of the Government and the contractor. The SOO is a summary of key goals, outcomes, or both, that allows competitors to propose their solutions, including technical approach and performance standards based upon commercial business practices.

(2) Technical Proposal Instructions

RFP Section L, Instructions, Conditions, and Notices to Offerors, informs prospective offerors that the proposal must be prepared in two parts: a technical and a business proposal, each part separate and complete in itself so evaluations of each may be performed independently of, and concurrently

with, the other. RFP instructions must be tailored on a case-by-case basis to ensure appropriate consideration of the specific acquisition, for example: capability to meet recruitment goals, model protocols and prior relative experience of the named staff. Technical proposals may include proposed direct costs. Offerors' estimates of personnel, equipment, facilities and other project costs are helpful indicators of their basic understanding of the RFP requirements. ICs may set page limits for technical proposals, resumes or other parts of the proposal.

(3) Technical Evaluation Factors

The PO must develop evaluation factors in consultation with review staff and submit them to the CO in the AP/RFC for inclusion in the RFP. Development of these factors and the assignment of the relative importance or weight to each require the exercise of judgment on a case-by-case basis because they must be tailored to the requirements of the individual acquisition. Because the factors will serve as a standard against which all proposals will be evaluated, it is imperative that staff choose them carefully to emphasize those considered to be critical in the selection of a contractor. The final evaluation factors contained in the RFP cannot be changed except by a formal amendment issued by the CO. No factors other than those set forth in the RFP may be used to evaluate proposals. The evaluation factors must be clear, concise, and fair so all potential offerors are fully aware of the bases for proposal evaluation. See HHSAR 315.204-5(c) for more details.

(4) Award Factors

The award decision is based on evaluation factors and significant subfactors tailored to the acquisition. RFPs must clearly inform prospective offerors of the relationship and relative importance of cost or price in comparison to other evaluation factors. The factors include Technical Merit, Cost, Past Performance, Small Disadvantaged Business Participation Plans and other non-cost factors. See FAR 15.304. The relationship is expressed in one of three ways:

> All evaluation factors other than cost or price, when combined, are (1) significantly more important than cost or price (customary for NIH R&D cost reimbursement contracts); (2) approximately equal to cost or price; or (3) significantly less important than cost or price.

(5) Other Considerations

a. NIH views mandatory qualifications or special contractor standards with concern because they restrict competition. Any such restrictions should be weighed carefully, and approved as part of the AP/RFC.

The RFP must provide the rationale for the restriction.

b. RFPs allow for submission of alternate proposals, provided the offeror also submits a proposal for performance of the RFP SOW/SOO. Alternate proposals may be considered if overall performance would be improved or not compromised, and if they are in the best interest of the NIH. See FAR 15.209(a)(2).
c. Solicitations issued under the Small Business Innovative Research (SBIR) program and as Broad Agency Announcements (BAAs) seek proposals based on broad categories or areas of interest to the Government rather than a specific SOW/SOO. Likewise, negotiation and award procedures under SBIRs and BAAs differ from "conventional" contract awards. See NIH Manual Chapters 6315-3 and 6035, respectively, for additional details.

f. Pre-Evaluation Procedures
   a. Receipt of Proposals

The CO must receive proposals by the RFP's published closing date and time. Proposals received after the published closing date and time are treated as Late Proposals, consistent with FAR 15.208. However, ICs that opt to include the Late Proposals and Revisions provision (HHSAR 352.215-70) in their solicitations may consider the Late Proposal under prescribed circumstances. See HHSAR 315.208.

The CO forwards the technical proposals to program and review staff. Direct cost data are provided but not proprietary cost data such as indirect costs and fees. A transmittal memorandum should convey, at a minimum, a list of offerors and the expected receipt date of the technical evaluation report, developed in conjunction with review staff during AP/RFC preparation. The PO also receives a copy of the business proposals.

COs are required to provide the DHHS Office of Research Integrity "ALERT System Manager" a list of principal investigator names for all research proposals received in the IC (see NIH Manual Chapter 6309-1).

The SRA is responsible for securing and controlling distribution of all proposals provided for use in the evaluation process. After the SRG meeting, all proposals must be accounted for by returning them to the SRA, disposing of them in a manner that preserves the confidentiality of the material, or filing them in an appropriate manner.

   b. Selection.Approval of Reviewers

Technical evaluation of biomedical and behavioral R&D contract proposals is the responsibility of review staff organizationally separate from pertinent program offices or operating divisions. SRGs must be selected in

accordance with Federal Advisory Committee Act (FACA), peer review regulations, conflict of interest and procurement integrity requirements. The PO cannot serve as a member of the SRG.

Each IC review component shall designate official(s) to supervise technical evaluations of biomedical and behavioral R&D contract proposals. These officials shall have the responsibility to develop and implement their organizations' evaluation procedures, assign SRAs to manage and conduct technical evaluation of proposals for specific acquisitions, approve SRG reviewers, designate presiding officials for SRG reviews, and develop procedures to ensure the confidentiality of materials and disposition of documents after reviews. Also, these officials ensure close communications among review, program, and contract management staffs, to promote mutual understanding of applicable policies and procedures.

While advisers with specific expertise in pertinent scientific disciplines and disease areas perform the technical evaluation, the SRA and CO are responsible for ensuring that evaluations follow review and acquisition regulation and policy standards. POs should discuss project requirements with SRAs to ensure that required disciplines are represented on SRGs. POs also should provide SRAs with names of potential reviewers with expertise in the required scientific or technical disciplines. However, no staff may directly or indirectly solicit names of potential reviewers from a source that is preparing a response to an RFP. SRAs are responsible for deciding review group memberships and are the only staff besides the CO who may communicate with actual or potential reviewers about the evaluation.

To ensure the integrity of the evaluation process, the SRA must remind potential reviewers that the number of proposals and identity of offerors cannot be revealed to anyone without the expressed written consent of the CO and SRA.

Before sending materials, SRAs must determine that reviewers have no known conflicts of interest with the offerors' organizations or investigators. See 42 CFR 52h and OER Web site http://grants1.nih.gov/grants/oer.htm. SRAs will send a description of the "NIH Conflict of Interest, Confidentiality and Non-Disclosure Rules for Reviewers" and accompanying Certification Form to be signed and returned immediately by all reviewers. The reviewer must certify that he or she has no conflicts of interest (other than those identified on the form) that are likely to bias his or her evaluation and that he or she will comply with procurement integrity requirements for non-disclosure of information. Further, he or she must agree to preserve the confidentiality of the review documents and proceedings.

If a reviewer subsequently identifies a conflict of interest, he or she should notify the SRA immediately to determine whether he or she should be disqualified as a reviewer. If no other qualified reviewer is available, the SRA may request a waiver to allow a reviewer having a conflict of interest with a particular proposal to participate in a SRG meeting and review other proposals recusing him/herself from the proposal(s) in conflict (per Class Deviation to HHSAR Subparts 315.608.73 through 315.608.78 approved April 27, 1999). Unless such a waiver is approved by the Deputy Director of Extramural Research, reviewers in conflict with one or more proposals may not participate in the peer review of the proposals in response to the same solicitation. See Delegation of Authority 1130, Program: General, No.29. https://delegations.nih.gov/DOADetails.aspx?id=1672

At the completion of the review meeting, the SRG members again must sign a certification document that he or she has complied with Conflict of Interest, Confidentiality and Non-Disclosure of Information rules.

c. Orienting/Briefing Reviewers

IC review staff should provide appropriate review instructions and background documents to SRG members to help them understand the program and rationale for the solicitation. These materials include relevant portions of the RFP, especially the SOW/SOO, technical proposal instructions, evaluation criteria and other program information included in the RFP.

The SRA and CO must ensure that all SRG members understand their roles and responsibilities in the competitive acquisition process, by providing written guidance emphasizing the:

- role of peer review in the acquisition process;
- judgment of each proposal independently based solely on the evaluation criteria reflecting the statement of work/statement of objective;
- restriction of evaluations to the specific solicitation and contents of the written proposals;
- evaluation and scoring of all proposals by all SRG members unless an appropriate waiver of conflict of interest has been obtained to permit recusal of specific reviewers;
- the score should reflect and be consistent with the strengths and weaknesses identified;
- identification of proposals' ambiguities, inconsistencies, deficiencies, and errors;
- need for reviewers to read proposals and provide written

documentation in support of their scores. Assigned reviewers will provide detailed reviews, including strengths and weaknesses with each evaluation criterion, as instructed;
- confidentiality of review materials and SRG deliberations;
- need to adhere to conflict of interest and procurement integrity regulations/policies;
- protection of vertebrate animals in research; and - NIH policies on human subject research, as applicable.

SRAs must caution reviewers that, as the RFP SOW/SOO already embodies prior peer-reviewed considerations of relevance, need, priority, and scientific/clinical rationale, their evaluations must not involve those factors.

Appropriate portions of the above guidance should be reiterated by the SRA/CO at the opening of the review meeting. SRAs/COs also should briefly explain the competitive range/award process so reviewers understand how their evaluations relate to subsequent procedures.

2. Technical Evaluation

The selected SRG performs the technical evaluation of all proposals in response to an RFP, guided by the SRA. Program staff or designees should attend review meetings within their respective responsibilities and provide technical, administrative, and/or program information essential for adequate review and evaluation. However, they may not be a member of the SRG nor join the technical discussions or recommendations concerning the proposals. All staff must avoid evaluative comments or indications of bias toward individual proposals. However, staff should privately alert the SRA when it appears that the reviewers have overlooked information contained in a proposal. Other program staff may attend review meetings with SRA concurrence.

a. Roles and Responsibilities

1) Contracting Officer

The CO or Contract Specialist (CS) must be present at all SRG meetings. They should address the SRG, as necessary, and serve as a resource on applicable regulations and policies. The CO should assist in ensuring a fair and objective review.

2) Scientific Review Administrator

The SRA must ensure that SRG members address all proposals and factors impartially and completely, basing their evaluations on proposals as submitted, and clarified by the CO as appropriate. SRG questions on scientific review should be addressed to the SRA, and questions on contract

policy are addressed to the CO or CS. The SRA ensures that recommendations and scores reflect the content and emphasis of the discussion.

3) Project Officer

Prior to the review of any proposals, the PO or representative summarizes the program background and purposes for the RFP and results desired from the contract. The PO also serves as a resource to explain programmatic points that SRG members may raise during the evaluation on the solicitation or contract. The PO cannot be a member of a peer review group (SRG) for the concept approval of a project or the technical evaluation of proposals.

4) Scientific Review Group Members

Before the meeting, all SRG members individually examine and evaluate all proposals and determine strengths and weaknesses relevant to the RFP evaluation criteria. These criteria serve as the standard against which all proposals responding to the RFP are evaluated. For each proposal, the SRG member may assign a preliminary score for each evaluation criterion guided by the acquisition objectives and the SOW/SOO. Comparisons between proposals are not permitted.

Topics for special consideration include, but are not limited to: concept reviews if not obtained previously, human subjects protections and inclusion of women, minorities and children in research, care and use of animals, biohazard protection. See section E.1.d., Special Considerations, (above) for additional topics for evaluation.

b. Technical Evaluation Process

At the SRG meeting, preliminary assessments serve as bases for discussing technical merit of the proposals. Assigned reviewers present narrative descriptions and critiques for each proposal assigned them, assessing strengths and weaknesses with each evaluation criterion, as well as identifying ambiguities, inconsistencies, deficiencies, and errors in the proposals. Other reviewers comment on and discuss their evaluations.

Peer reviewers may provide recommendations about offerors' direct costs in certain judgmental areas, for example, hours in specific staffing categories or needs for specific supplies or equipment. When reviewers express concerns about direct cost estimates, such concerns should be identified and discussed in the Technical Evaluation Report (TER) to alert the CO to potential issues in the cost realism evaluation.

If sudden exigencies prevent any SRG members from participating, those members may not contribute final votes for acceptability or scoring. However, they should be encouraged to submit written comments, using available physical or electronic means to provide their opinions to the meeting. These comments should be shared with the SRG members present and incorporated into the TER.

After general discussion, all participating SRG members individually score each proposal on all evaluation criteria, based on corresponding weights published in the RFP. They should refine their comments on specific strengths and weaknesses for all evaluation criteria, reflecting their written judgments of strengths or weaknesses derived from the discussion.

When reviewers participate by teleconference, they will be permitted to vote and score proposals and will submit their individual evaluations, recommendations, votes and scores by mail, electronic means, or fax. The SRA records the results of their vote in the TER.

The final SRG meeting tasks are to determine the technical acceptability/unacceptability and rankings of proposals. If an offeror's proposal indicates sufficient technical understanding and capabilities, the members should recommend that it is acceptable. If, on the other hand, the proposal demonstrates a significant lack of understanding or ability to perform required tasks, it should be considered unacceptable. The SRG should consider the potential for correcting minor weaknesses or deficiencies. However, proposals rated as acceptable should not require major revisions. Use of predetermined cut-off scores is not permitted.

An SRG votes on the acceptability of a proposal, and must provide the individual members' written comments and determination on acceptability/unacceptability as described above. For SRGs, the SRA includes the ranking in the TER. The SRGs' tasks are complete following the acceptability determinations.

The SRA and/or CO check each rating sheet for completeness and total the scores for each proposal. The SRA or CO develops a composite technical ranking. Ranking is accomplished by totaling the numerical scores from all SRG members for the evaluation criteria and calculating average ratings for each offeror.

In the event of a tie vote on a proposal's acceptability/unacceptability, the SRA will ask for reconsideration. After reasonable further discussion, if the tie remains, the proposal shall be considered acceptable.

c. Technical Evaluation Support

The SRA is responsible for the TER and shall prepare technical evaluation summaries for all proposals, documenting strengths and weaknesses, on a criterion-by-criterion and overall basis. The documented strengths, weaknesses

and recommendations serve as the basis for later discussions with those offerors in the competitive range. The report reflects rankings and scores of each proposal and identifies each as acceptable or unacceptable.

Careful preparation of the TER is important as program and contracting staffs use the information as the basis to develop negotiation strategies and to debrief unsuccessful offerors.

The original report and any appendices shall be delivered to the CO, with a copy to the PO.

3. Business Evaluation

The business evaluation of proposals, at a minimum, involves both the CO and PO.

FAR Subpart 15.304 (c)(1), requires that the Government evaluate cost or price in every source selection. In addition, FAR requires the Government to evaluate and address in every source selection the quality of an offeror's proposal through consideration of one or more non-cost evaluation factors such as technical excellence, past performance, compliance with the solicitation requirements, personnel qualifications, management capability and prior experience. Evaluation of the above factors is required in all source selection decisions, and depending on the nature of the requirement itself, these could be combined with other non-cost award factors such as past performance and the extent of participation of small disadvantaged business concerns.

Prospective offerors' must be apprised of the relative significance or importance of cost or price as related to all other non-cost evaluation factors.

COs are to evaluate business proposals adhering to the requirements for cost or price analysis as addressed in FAR 15.404-1. The objective of cost or price analysis is to ensure that the final agreed-to price is fair and reasonable. The CO is responsible for evaluating the reasonableness of the offered price.

Various analytical techniques and procedures can be used to ensure that the final price is fair and reasonable. The predominant analysis techniques used in the award of R&D type contracts include: cost analysis, cost realism analysis and price analysis, usually combined with some form of technical analysis. These techniques may be used singularly or in combination with one another. The complexity and circumstances of each acquisition will determine the type and level of detail of the analysis required.

Cost analysis is the process of evaluating the reasonableness of the separate and individual cost elements and profit of an offeror's proposal and the application of judgment to determine how well the proposed costs represent what the cost of the contract should be, assuming reasonable economy and efficiency. There are various cost analysis techniques and procedures that can be used to ensure a fair and reasonable price and these are discussed at FAR 15.404-1(c).

Cost realism analysis is the process of independently reviewing and evaluating specific elements of each offeror's proposed estimated cost to determine whether the estimated proposed cost elements are realistic for the work to be performed; reflect the offeror's clear understanding of the requirements; and are consistent with the unique methods of performance and materials described in the offeror's technical proposal (FAR 15-404-1(d)). Cost realism analysis must be performed whenever a cost-reimbursement type contract is contemplated. Cost realism analysis is used to determine the "probable cost of performance." The probable cost of performance may differ from the offeror's proposed cost and reflects the Government's best estimate of the cost of the contract that is most likely to result from the offeror's proposal. The probable cost of performance is determined by adjusting each offeror's proposed cost, and fee when applicable, to reflect any additions or reductions in cost elements to realistic levels based on the results of the cost realism analysis.

Price analysis is the process of examining and evaluating a proposed price without evaluating its separate cost elements and profit. Normally, adequate price competition establishes price reasonableness. Therefore, when contracting on a firm fixed-price basis, comparison of proposed prices will usually satisfy the requirement to perform a price analysis. Examples of price analysis techniques can be found at FAR 15.404-1(b).

FAR 15.404-1(e) refers to technical analysis as a process where the CO seeks input of persons having specialized knowledge, skills, and experience (typically POs and SRG members) to assist in determining the need and reasonableness of the offeror's proposed types and quantities of labor hours and labor mix, materials, equipment, supplies, consultants, travel, subcontracts, etc. Opinions are sought as to whether these elements, in terms of their type and quantity, are necessary and reasonable for efficient contract performance. This analysis is usually implemented, in part, by completion of the Project Officer Technical Questionnaire (POTQ), Form NIH – 2497. NIH Manual 6015-1, entitled: Financial Analysis of Contract Proposals and Modifications, requires that a POTQ be completed "in all instances where the acquisition is expected to result in an award of $550,000 or more and a cost realism/cost analysis is performed." Responsibility for completion of the POTQ rests jointly with the PO and CO.

In conjunction with evaluating cost or price reasonableness, the CO must determine the responsibility of a prospective contractor under FAR 9.104-1.

4. Award Without Discussion

The CO may determine that it is in the Government's best interest to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). This action is authorized if the solicitation included the appropriate notification to offerors found in FAR 52.215-1.

5. Competitive Range

a. Source Evaluation

Following receipt of the TER from review staff, the CO and PO confirm proposal strengths and weaknesses and identify ambiguities, inconsistencies, deficiencies, errors, and additional program-based issues, which should be addressed in discussions with specific offerors in the competitive range.

The CO or PO may seek relevant technical expertise not directly connected with the acquisition if support is needed; however the CO must ensure adherence to conflict of interest and confidentiality concerns.

Only proposals judged acceptable by the SRG may be considered further for discussions and award.

If the CO or PO identifies significant actual or apparent oversights, inaccuracies, or errors in the SRG evaluation, he or she must document those concerns and, after appropriate consultation, obtain further peer evaluation of the proposals. A new SRG may be necessary.

Depending on the nature of items to be discussed, the CO may decide to conduct site visits at the offerors' facilities (see below).

b. Establishing Competitive Range

Based on the ratings of each proposal against all evaluation criteria, the CO shall establish a competitive range comprised of all of the most highly rated proposals, unless the range is further reduced for purposes of efficiency pursuant to FAR 15.306(c)(2).

The CO prepares a written Competitive Range document based on review findings and provides a complete rationale for decisions to include or exclude specific proposals from the range. The CO then notifies offerors excluded from the range, advises them that no discussions or negotiations will be undertaken and revisions to their proposals will not be accepted.

Offerors excluded from the competitive range may seek a debriefing before award under FAR 15.505.

c. Technical and Business Discussions

When negotiations are conducted in a competitive acquisition, they take place after establishment of the competitive range and are called discussions. If discussions are held with any offeror in the competitive range, they must be held with all in the range. Site visits may be considered as included within the technical and business discussions and generally involve oral discussions.

Discussions are tailored to each offeror's proposal, and conducted by the CO or CS with each offeror within the competitive range. Program officials, cost analysts, attorneys and others as necessary, may assist them. To provide continuity, SRG members may assist in competitive range discussions and subsequent evaluations, as appropriate.

The primary objective of discussions is to maximize the Government's ability to obtain best value, based on the requirement and the evaluation factors set forth in the solicitation.

The CO shall:

- control all discussions;
- advise offerors of significant deficiencies, ambiguities, inconsistencies, adverse past performance (FAR 15.306(d)(3)), errors and other uncertainties of the proposals;
- provide opportunity for offerors to submit technical, cost/price, or other corrections to fully satisfy the RFP requirements; and
- address compliance with all applicable Human Subject and Animal Welfare issues and policies as needed.

FAR 15.306 places limits on exchanges by prohibiting Government personnel from conduct that:

1) Favors one offeror over another;
2) Reveals an offeror's technical solution, including unique technology, innovative and unique uses of commercial items, or any information that would compromise an offeror's intellectual property to another offeror;
3) Reveals an offeror's price without that offeror's permission. However, the CO may inform an offeror that its price is considered by the Government to be too high, or too low, and reveal the results of the analysis supporting that conclusion. It also is permissible, at the Government's discretion, to indicate to all offerors the cost or price that the Government's price analysis, market research, and other reviews have identified as reasonable (41 U.S.C.423(h)(1)(2));
4) Reveals the names of individuals providing reference information about an offeror's past performance; or
5) Knowingly furnishes source selection information in violation of FAR 3.104 and 41 U.S.C.423(h)(1)(2).

Some acquisitions may require more than one round of discussions with offerors in the competitive range depending on the size, complexity and significance of the acquisition, available time, expense and administrative limitations.

When oral discussions are held, staff must document essential points in the conversations and provide each offeror the opportunity to submit a written response addressing issues from the discussions.

The CO may request or allow proposal revisions to clarify and document understandings reached during negotiations. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a Final Proposal Revision (FPR). The CO is required to establish a common cut-off date only for receipt of FPRs. Requests for FPRs shall advise offerors that the FPRs shall be in writing and that the Government intends to make award without obtaining further revisions.

d. Preaward Site Visits

Preaward site visits may be necessary to: assess information regarding certain offerors' capabilities, resources, organization, and facilities; verify the offeror's proposal in the areas deemed necessary; and clarify necessary proposal details unfamiliar to evaluators. Not all offerors must be site visited.

The CO/CS should conduct preaward site visits together with appropriate program staff. The CO/CS is responsible for conducting and documenting site visits and oral discussions. However, program staffs take the lead in conducting and documenting technical aspects of the proceedings, including selecting appropriate reviewers to participate in the site visits. These may include SRG members. Reports from individual reviewers should be provided to the CO/CS or program staff for preparation of site visit reports.

6. Consideration for Award

a. Final Evaluation/Recommendations

After receipt of FPRs, the CO and PO conduct a final evaluation of technical, cost/price, and other salient factors, assisted by a Source Selection Panel (SSP), as the IC deems necessary. The CO appoints the SSP, using recommendations from the PO.

The SSP's final evaluations must apply the same criteria for the final evaluations of the FPRs as those used in the initial technical evaluation of proposals, and any other factors announced in the RFP. New information obtained during discussions may provide sufficient justification to rescore proposals.

b. Contractor Selection

The SSP recommends in writing to the CO which source(s) it judges can perform the contract in a manner most advantageous to the Government, price and other factors considered as described in the RFP. The CO has statutory authority for award selection.

Special program constraints may be considered in selection, e.g., need for geographical distribution, different population mixes in clinical studies, or different technical approaches to a problem, provided the RFP made those factors known.

In all cases, contract files must document the rationale for award decisions. The CO conducts postaward debriefings after receipt of timely, written requests by successful or unsuccessful offerors. See FAR 15.506.

c. Finalization of Details

After selection of the successful proposal, finalization of details with the selected offeror may be conducted if deemed necessary. However, no factor that could have any effect on the selection process may be introduced after the common cutoff date for receipt of FPRs. The finalization process shall not in any way prejudice the competitive interest or rights of the unsuccessful offerors. Finalization of details with the selected offeror shall be restricted to definitizing the final agreement on terms and conditions, assuming none of these factors were involved in the selection process. The CO must exercise caution to ensure that the finalization process is not used to change the requirements contained in the solicitation, or to make any other changes that would impact on the source selection decision. See HHSAR 315.370.

d. Contract Preparation and Award

After finalization of details, the Contracting Officer must prepare the negotiation memorandum and contract document. The contract must contain all agreed to terms and conditions and clauses required by law or regulation. After receiving the required approvals, the contract should be transmitted to the prospective contractor for signature. The contract is not effective until accepted by the CO. See HHSAR 315.371 and 315.372 for additional details.

The CO must follow agency procedures regarding Departmental and Congressional notification of awards in addition to the FedBizOpps synopsis requirements included in FAR Part 5.

F. Procedures: Acquisition By Other Than Full and Open Competition

While this Manual Chapter emphasizes competitive solicitations, review and evaluation principles above generally apply to both solicited and unsolicited proposals obtained by other than full and open competition. Some differences exist in the handling of these proposals as protecting the integrity of the competitive process is not an issue. However, the CO and PO still must maintain the confidential nature of the information, Procurement Integrity prohibitions, and prohibition against disclosing proprietary information. Guidance for

processing a Justification for Other than Full and Open Competition (JOFOC) is contained in the JOFOC Desk Guide for NIH Contracts at the following Web site: http://www3.od.nih.gov/ocm/contracts/PDF/JDG2_99.pdf

1. Solicited Proposals
    a. New Contracts

        When the NIH solicits a contract proposal directly from a source without competition, it first must establish that the source is the only one that can realistically perform the specific requirement, and that the solicitation is otherwise justified within the FAR and HHSAR. Peer reviews for R&D project concepts and proposals are required as for competitive proposals (see 42 CFR 52h.10). Given that competitive selection of sources based on uniform evaluation criteria does not apply, the RFP need not include formal criteria. However, these are useful both to offerors in preparing proposals to meet NIH requirements, and reviewers in assessing capabilities. Absent formal evaluation criteria, reviewers will concentrate on technical methodology, organizational and staff qualifications, proposed resources, and other factors relevant to the source's ability to meet the contract requirements.

    b. Existing Contracts

        With certain exceptions, extensions of existing contracts also must be approved within HHS acquisition guidelines before proposals are solicited without competition. Extensions may aim to continue or complete work on the same project, or may introduce expanded or changed approaches or subject matter.

        Extensions to continue work under cost-reimbursement completion contracts do not require JOFOCs, provided that previous concept reviews defined those efforts. Extensions to allow additional effort on level-of-effort term contracts do require JOFOCs. In addition, extensions for expansions or changes in work may require prior concept reviews, depending on the circumstances. See section F.1.a., above. The requirement for peer review shall be evaluated on a case-by-case basis pursuant to 42 CFR 52h.
2. Unsolicited Proposals

    Unsolicited proposals allow unique and innovative ideas or approaches that have been developed outside the Government to be made available to Government agencies for use in accomplishing their missions. Unsolicited proposals are offered with the intent that the Government will enter into a contract with the offeror for research and development or other efforts supporting the Government mission, and often represent a substantial investment of time and effort by the offeror.

Under FAR Subpart 15.6, a valid unsolicited proposal must:

a. Be innovative and unique;

b. Be independently originated and developed by the offeror;
c. Be prepared without Government supervision, endorsement, direction or direct Government involvement;
d. Include sufficient detail to permit a determination that Government support could be worthwhile and the proposed work could benefit the agency's research and development or other mission responsibilities; and
e. Not be an advance proposal for a known agency requirement that can be acquired by competitive methods.

The IC Chief Contracting Officer is the designated point of contact for unsolicited proposals. See FAR 15.606. Unsolicited proposals determined to be invalid shall be returned to the offerors.

If it is determined that an unsolicited proposal is valid, both the project concept and approach must be peer reviewed by three or more experts.

The CO may commence negotiations on a sole source basis only when:

a. an unsolicited proposal has received a favorable comprehensive evaluation;
b. a justification and approval has been obtained (see FAR Subpart 6.3);
c. the agency technical office sponsoring the contract furnished the necessary funds; and
d. the CO has complied with the synopsis requirements of FAR Subpart 5.2.

Only the cognizant CO may bind the Government regarding unsolicited proposals. See FAR 15.604(b).

G. References

Numerous references provide background for this issuance:

1. Public Health Service Act as amended, December 31, 1987, Sections 405 and 492;
2. Title 48 of the Code of Federal Regulations (48 CFR), Federal Acquisition Regulation (FAR): Part 15, Contracting by Negotiation, FAR Part 35, Research and Development Contracting http://www.acqnet.gov/far/current/html/FARTOCP01.html ;
3. FAR 15.204-1, Uniform Contract Format;
4. HHS Acquisition Regulation (HHSAR), 48 CFR 315, Contracting by Negotiation http://www.hhs.gov/ogam/oam/procurement/hhsar.html;
5. HHS Regulations, 45 CFR, Part 11, Committee Management;
6. Public Health Service Regulations, 42 CFR Part 52h, Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects;
7. NIH Manual Chapter 1805, Use of Advisors in Program and Project Review and Management
8. NIH Manual Chapter 1810-1, Procedures for Avoiding Conflict of Interest for NIH Special Government Employee (SGE) Advisory Committee Members

9. NIH Manual Chapter 1825, Information Collection from the Public
10. NIH Manual Chapter 26307-1/6307-1 Organization of Contracting Responsibilities
11. NIH Manual Chapter 6015-1, Financial Analysis of Contract Proposals and Modifications
12. NIH Program Administrators' Handbook, 1995. DHHS Project Officers' Contracting Handbook; http://www.knownet.hhs.gov/acquisition/POHandbookSTD.doc
13. Inclusion of Children in Clinical Research. http://grants.nih.gov/grants/funding/children/children.htm
14. Inclusion of Women and Minorities as Participants in Clinical Research. http://grants1.nih.gov/grants/funding/women_min/women_min.htm;
15. OER Policy Announcement on Peer Review http://grants1.nih.gov/grants/peer/peer.htm#documents;
16. NIH Manual Chapter 6380-1, Human Subject Policies for R&D Contracts.
17. NIH Manual Chapter 6380-2/54206, Responsibility for Care and Use of Animals.
18. NIH Manual Chapter 6035, Broad Agency Announcements
19. NIH Manual Chapter 6315-3, Technical Evaluation of Proposals Submitted in Response to SBIR Contract Solicitations
20. Past Performance Information Retrieval System http://www.ppirs.gov/;
21. NIH Form 1688-1, Project Objectives, available at: http://forms.nih.gov/adobe/contracts/NH1688_1.PDF. Also see http://projectreporter.nih.gov/reporter.cfm; and
22. Responsible Conduct of Research http://ori.dhhs.gov/html/programs/rcr_requirements.asp.

H. Definitions

(listed alphabetically)

1. **Acceptable Proposal**

   A proposal judged to be complete in itself, to contain no major deficiencies, and to present sufficient evidence to indicate that the offeror is capable of satisfying the minimum requirements of the Request for Proposal (RFP) and thus is eligible for consideration for (a) inclusion in a competitive range for a competitive acquisition or (b) award in the case of a noncompetitive acquisition.

2. **Broad Agency Announcement (BAA)**

   A general announcement of the organization’s researchinterest including criteria for selecting proposals and soliciting the participation of all offerors capable of satisfying the Government’s needs (see FAR 2.101 and FAR 6.102(d)(2)).

3. **Clinical Trial**

For purposes of proposal review, NIH defines a clinical trial as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments or devices).

4. **Competitive Range**

   The most highly rated technically acceptable proposals unless the range is further reduced for efficiency (see FAR 15.306(c)).

5. **Evaluators**

   Any individuals, including Government employees, who participate in scientific or technical reviews of contract and subcontract proposals, or active projects under NIH awards, and who assign scores or ratings, or make funding recommendations. This includes members of SRGs and SSPs or any participants performing these evaluation functions. During their involvement in the evaluation process, evaluators are considered critical participants in the acquisition. As such, the applicable Standards of Conduct, Procurement Integrity, and Confidentiality and Non-Disclosure of Information bind them.

6. **Interagency Agreement**

   A written arrangement between one or more NIH components and one or more government entities outside the NIH, all of which must have the statutory authority to engage in the arrangement. Such agreements may include, but are not limited to, arrangements to receive and/or provide services, supplies, advice and counsel, involving the exchange of funds.

7. **Intra-agency Agreement**

   A written arrangement between/among NIH components, all of which must have the statutory authority to engage in the arrangement.

8. **Performance-based contracting**

   All aspects of an acquisition are structured around the purpose of the work to be performed with the contract requirements set forth in clear, specific, and objective terms with measurable outcomes as opposed to either the manner by which the work is to be performed or broad and imprecise statements of work (see FAR 2.101).

9. **Program Advisory Group (PAG)**

   A peer review group which reviews and approves or disapproves concepts for R&D contract projects.

10. **Proposal Deficiency**

A material failure of a proposal to meet a Government requirement or a combination of significant weaknesses in a proposal that increases the risk of unsuccessful contract performance to an unacceptable level.

11. **Proposal Weakness**

A flaw in the proposal that increases the risk of unsuccessful contract performance. A "significant weakness" in the proposal is a flaw that appreciably increases the risk of unsuccessful contract performance.

12. **Research and Development (R&D)**

Research, development, and demonstration activities typically involve procedures to acquire and apply new scientific knowledge and to:

- develop approaches and methods;
- perform experimental procedures;
- record observations and data;
- analyze and interpret findings; and
- publish results, interpretations, and conclusions.

The spectrum of biomedical and behavioral research, development, demonstration, and R&D support activities are defined as follows:

a. Research

Systematic search or intensive study directed towards achieving new or fuller scientific knowledge or understanding beyond the state of the art, and/or towards the practical application of knowledge/understanding to advance specific program objectives.

b. Development

Systematic use of knowledge gained from research to create useful materials, devices, systems, or methods.

c. Demonstration

Systematic studies of the feasibility of disseminating or applying R&D findings to community or other group situations, e.g., establish effectiveness of health diagnosis, treatment, or prevention approaches to improve public health.

d. R&D Support

Procedures, techniques, and activities directly supporting the conduct of R&D, involving innovative or standard methodologies to prepare or provide special materials, resources, or services integral to performing R&D projects, e.g., screen or test components for biological activity; collect, provide, analyze, or interpret experimental research data or information, or provide significant enhancements to existing equipment or systems.

13. **R&D Contract Project**

An identified, circumscribed activity, involving a single contract or two or more similar, related, or interdependent contracts intended and designed to acquire new or fuller knowledge and understanding in the areas of biomedical or behavioral research and/or to use such knowledge and understanding to develop useful materials, devices, systems or methods.

14. **R&D Contract Proposal**

A written offer to enter into a contract that is submitted to the appropriate agency official by an individual or nonfederal organization which includes, at a minimum, a description of the nature, purpose, duration, and cost of the project, and the methods, personnel and facilities to be utilized in carrying it out. A contract proposal may be unsolicited by the federal government or submitted in response to a Request for Proposals. It consists of a technical proposal and a business proposal.

15. **R&D Project Concept**

The basic purpose, scope, and objectives of a project. The scope may include estimates of the total costs and time needed for completion of the project.

16. **Scientific Review Administrator (SRA)**

The NIH official who has the responsibility to ensure that contract proposals receive a competent, thorough and fair review by an SRG, consistent with all relevant NIH review policies. The SRA organizes and provides scientific/technical support to the SRGs, and is responsible for the completeness and accuracy of the TER, including votes on acceptability, scoring of proposals, and other recommendations to the PO and CO.

17. **Scientific Review Group (SRG)**

A group of primarily nongovernmental experts qualified by training and experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review, to give expert advice on the scientific and technical merits of contract proposals, or the concept of contract projects when serving as a PAG. A minimum of three reviewers is required. Not more than one-fourth of the SRG may be officers or employees of the United States.

Membership on such groups does not make an individual an officer, agent, or employee of the United States.

IC staffs are ineligible to participate as members or SRAs of SRGs evaluating and recommending on specific contract proposals or projects, for which they have had or may have other selection, award, or administrative responsibilities. IC staff may serve as policy or technical resources to the SRG.

18. **Source Selection Panel (SSP)**

    A generic term for an IC panel that evaluates the Final Proposal Revisions and recommends to the CO who should receive an award. The SSP may comprise, at a minimum, the project and contracting officers, and may be supplemented by other persons with appropriate technical expertise.

19. **Special Emphasis Panels (SEPs)**

    A type of Scientific Review Group established under FACA in response to review needs. SEPs normally consist of a minimum of five members; the exact number depends on the size, complexity, and number of proposals under review.

20. **Technical Evaluation Report (TER)**

    A report prepared and furnished to the CO by the SRA and maintained as a permanent record in the contract file. The report must reflect the ranking of the proposals and identify each proposal as acceptable or unacceptable. The report also must include a narrative evaluation specifying the strengths and weaknesses of each proposal, a copy of each signed rating sheet, and any reservations, qualifications, or areas to be addressed that might bear upon the selection of sources for negotiation and award. Concrete technical reasons supporting a determination of unacceptability with regard to any proposal must be included. The report also must include specific points and questions, which are to be raised in discussions or negotiations.

21. **Unacceptable Proposal**

    A proposal judged to contain deficiencies, which are so material as to preclude any possibility of upgrading it to a competitive level except through major revisions and additions, which would be tantamount to the submission of another proposal.

I. Records Retention and Disposal

All records pertaining to this Chapter should be retained as described in FAR 4.805 at a minimum. All records (e-mail and non-e-mail) pertaining to this Chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records," Appendix 1, 'NIH Records Control Schedule,' Item 2600-A-4, Routine Procurement Files.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

J. Internal Controls

The purpose of this manual issuance is to identify issues to be considered by the NIH contracting activities in awarding R&D contracts.

1. **Offices Responsible for Reviewing Internal Controls Relative to this Chapter**: The Division of Acquisition Policy and Evaluation, Office of Acquisition Management and Policy, OA and the Office of Extramural Programs, Office of Extramural Research, OD.
2. **Frequency of Review:** On-going review.
3. **Method of Review:** The Division of Acquisition Policy and Evaluation, Office of Acquisition Management and Policy, will maintain appropriate oversight through reviews of the IC contract files conducted by the NIH Board of Contract Awards (Board). The NIH Board reviews a percentage of contract actions from each IC. Issues identified by the NIH Board are provided to the IC for corrective action. The Office of Extramural Programs, OER, will be consulted as necessary. When repetitive issues are identified, these are brought to the attention of the Acquisition Management Committee, which is responsible for addressing and resolving common acquisition issues. In addition, the Head of the Contracting Activity (HCA) is routinely apprised of any difficulties in the IC implementation of policy. Depending on the nature and extent of the problem, the HCA may recommend additional review, policy guidance and/or training of the contract staff.
4. **The Year-End Summary Report of Repetitive Issues will be sent to** the NIH Chief Contracting Officers, the Deputy Director for Management, and the Deputy Director for Extramural Research.

Appendix - Sequence Of Steps In The Development Of Projects And Award Of New Competitive R&D Contracts

- Project Concept Development
- Concept Peer Review
- Acquisition Plan/Request for Contract
- Request for Proposals
- Receipt of Proposals
- Scientific Review Group Meeting
- Business Evaluation
- Technical Evaluation Reports
- Cost/Price Realism and Analysis*
- Competitive Range Determination*
- Competitive Range Discussions
- Site Visits*
- Negotiation Plan
- Final Negotiations*
- Final Proposal Revisions
- Source Selection Panel
- Source Selection
- Finalization of Special Considerations*
- Finalization of Details*
- Contract Award

*As Applicable