

NIH POLICY MANUAL

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1. Explanation of Material Transmitted: This Manual Chapter provides updated guidance on the selection and submission of Presolicitation and Preaward files to the NIH Board of Contract Awards for review.

2. Filing Instructions:

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**PRESOLICITATION AND PREAWARD REVIEW AND APPROVAL OF
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A. PURPOSE

This NIH Manual Chapter implements the requirements of the Health and Human Services Acquisition Regulation (HHSAR) (48 C.F.R. Chapter 3) 304.71. It requires the Head of the Contracting Activity (HCA) to establish review and approval procedures for proposed contract actions to ensure that: (1) each action is in conformance with law, established policies and procedures, and sound business practices; (2) each contract action properly reflects the mutual understanding of the parties; and (3) the Contracting Officer (CO) is informed of deficiencies and items of questionable acceptability, and corrective action is taken.

B. BACKGROUND

The Federal Acquisition Regulation (FAR)(48 C.F.R. Chapter 1) requires the agency head or designee to oversee their agency's acquisition system. HHS implements this requirement, in part, through HHSAR 302.101, Definitions, and HHSAR 304.71, Review and Approval of Proposed Contract Awards. Under HHSAR 304.71, the HCA must establish review and approval procedures for all contract actions. To enable the HCA to fulfill the requirement, NIH has established the NIH Board of Contract Awards (Board).

C. POLICY

NIH policy implements the acquisition oversight requirements of the FAR and the HHSAR by performing presolicitation and preaward reviews of contract files through the Board. This policy establishes the parameters for the Board reviews and the procedures under which it operates.

D. REFERENCES

1. FAR 2.101, Definitions
2. FAR 7.103, Agency-head responsibilities
3. FAR 7.105, Contents of written acquisition plans
4. HHSAR 302.101, Definitions
5. HHSAR 304.71, Review and Approval of Proposed Contract Awards

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6. HHSAR 307.71, Acquisition Plan
<http://www.hhs.gov/oamp/policies/acquisitionplanchanges.pdf>
7. NIH Manual Issuance [6315-1](#), Initiation, Review, Evaluation, and Award of Research & Development (R&D) Contracts

E. APPLICABILITY OF REVIEWS

The Office of Acquisition and Logistics Management (OALM) shall review files from all NIH Offices of Acquisitions (OA) in accordance with the procedures stated in Section G., Selection of Files for Review.

F. REVIEWERS

1. The Board Chair is the Director, Division of Acquisition Policy and Evaluation (DAPE).
2. The Chair determines the composition of the Board on a case-by-case basis. In addition to the Chair, the Board typically includes one procurement analyst for presolicitation reviews. For preaward reviews, the Board typically includes a procurement analyst and a financial analyst.
3. As needed, the Chair may call upon subject matter experts, e.g., staff of the: Office of Extramural Research, Office of Technology Transfer, Office of the General Counsel (OGC), Center for Information Technology, HHS Office of Small & Disadvantaged Business Utilization, and other disciplines to provide advice to the Board. The Chair also may request that a staff member from an OA, who has significant experience with the types of requirements under review, serve on an ad hoc basis.
4. The Chair may request the OA Directors to assign senior Contract Specialists to serve on the Board for cross-training purposes or to assist in reviews as necessary. Individuals so assigned may not participate in a review of a requirement originating in their OA.

G. SELECTION OF FILES FOR REVIEW

The OA Directors are responsible for selecting files from their respective offices for review by the Board with the exception of files designated by the HCA under

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G.2., Mandatory Review and G.3., Judgmental Samples identified below. The Directors may select files for a presolicitation review, a preaward review, or both.

1. Selection Criteria

This selection process ensures that the Board reviews a broad spectrum of the kinds and types of awards made by the OAs during a given fiscal year. Files submitted for presolicitation review may be for awards either in the current fiscal year or in the next fiscal year. The OA Directors have broad discretion to select files for review by the Board. The Directors should consider selecting actions that fall into the following categories:

- requirements estimated to exceed \$500,000;
- performance-based acquisitions;
- innovative approaches to contracting;
- requirements which have a high risk/impact on the public;
- special patent or data rights issues;
- hybrid contract types;
- construction management contracts;
- design-build requirements; and
- sealed-bid requirements when the proposed award is to other than the low bidder.

The OA Directors also should consider other issues such as workload distribution between teams and COs and types of awards. Selected files should represent the commodities and services obtained by each OA.

When selecting files for review, note that generally the Board will not review Small Business Innovation Research (SBIR) Phase I files as they are fixed-price and of relatively small dollar value. The Board may review SBIR Phase I files only when, in the opinion of an OA Director, there are special circumstances and he/she obtains the prior approval of the Chair.

2. Mandatory Review

OAs must submit all multiple award actions pursuant to FAR 16.5 and multi-agency/Government-wide Agency contracts for Board review at the presolicitation stage. At the discretion of the Chair, one or more of the proposed new awards may require follow-up preaward review by the

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Board. Generally, the Board will consider a 25% sample appropriate for review.

3. Judgmental Samples

At the direction of the HCA, the Chair may identify a single contract or select a judgmental sample of contracts for review from specified OAs. An example of judgmental sampling is if the HCA wishes to conduct a special subject review in a single OA or across several OAs.

4. Number of Files for Review

The total number of files submitted for review should equal approximately ten percent of the average number of new awards (excluding SBIR Phase I contracts) for the previous three fiscal years, with a minimum of one file per year from each OA. For purposes of determining the average and number of files for review, the Board excludes SBIR Phase I awards. In addition, the Chair may adjust the total upward or downward in conjunction with the HCA, based on unusual or extenuating circumstances.

If an OA Director believes that extenuating circumstances warrant either an increase or decrease in the review number, he/she must submit a written request to the Chair explaining the extenuating circumstances. The final decision for determining the number of files for review during a given fiscal year rests with the HCA.

H. NOTIFICATION AND SUBMISSION OF CONTRACT FILES

1. Each OA Director must provide a list of files nominated for Board review to the Chair by November 30 of each year. He/she should base the number of files for Board review in accordance with G.4 above. OA Directors must submit a revised list to the Chair whenever any significant delays from planned submissions arise and identify substitute actions as needed. OA Directors are encouraged to submit files for review throughout the fiscal year and not clustered into one quarter. (See J. Records Retention and Disposal)

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2. The list of files must indicate the:
 - title of the project;
 - nature of the project, (e.g., clinical trial, construction, or other category);
 - type of review: presolicitation or preaward;
 - estimated dollar value of the project;
 - anticipated or actual release date of the Request for Proposal (RFP) and anticipated the date of award; and
 - approximate date for submission of the file to the Board.
3. The OAs shall submit files to the DAPE, Room 6C01, 6100 Executive Blvd., Rockville, MD 20892 (USPS) or 20852 (courier), Mail Stop 7540, Attention: NIH Board of Contract Awards. (See J. Records Retention and Disposal)
4. The OAs shall allow 5 working days for presolicitation reviews and 7 working days for preaward reviews. Files received before 12 noon are logged in as of the day received. Files logged in after 12 noon are logged in as of the following work day.
5. The fiscal year-end deadline for receipt of presolicitation and preaward files is 15 working days before the end of the fiscal year. Exceptions to the deadline require prior approval of the Chair.
6. The OAs shall not release the solicitations on actions submitted to the Board for presolicitation review until the Board issues its Minutes and all substantive issues are resolved.
7. The OAs shall not award contracts submitted to the Board for preaward review until the Board issues its Minutes and all substantive issues are resolved.

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8. Documentation Required for Review

a. Presolicitation Reviews

The OAs must provide the Board with the Acquisition Plan using the format prescribed by HHSAR 307.71. The Board will focus its review on the:

- Statement of Work;
- Independent Government Cost Estimate;
- Concept Review (when applicable);
- proposed or actual *FedBizOpps* Announcement(s);
- completed HHS Small Business Review Form HHS 653;
<http://www.hhs.gov/osdbu/read/HHS653SmallBusReviewForm.doc>
- internal review documents and responses/resolution of issues; and
- full solicitation (and amendments).
Solicitations may be made available online.

Internal file reviews for presolicitation actions must document a thorough review by other than the Contract Specialist/CO responsible for drafting/negotiating the acquisition. The OAs must make all corrections as a result of the internal review and document them prior to submission to the Board.

OAs may submit original documents or copies of presolicitation files at the discretion of the CO. Original documents will be returned with the Board's Minutes. (See J. Records Retention and Disposal)

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b. Preamward Reviews

The OAs must provide the Board with the entire preaward contract file. COs must review FAR 4.803, Contents of contract files, when determining appropriate documentation to include for preaward contract files. However, the OAs need only furnish a list of the unsuccessful offerors, not proposals.

Internal file reviews for preaward actions must document a thorough review by other than the Contract Specialist/CO responsible for drafting/negotiating the acquisition. In accord with HHSAR 304.7101, "if any official is to serve as the CO and signs the contractual document, the review and approval function must be performed by an appropriate official at least one level above." The OAs must make all corrections as a result of the internal review and document them prior to submission to the Board.

The OAs shall submit decisional documents such as the Summary of Negotiations and the Source Selection Document as unsigned drafts to facilitate incorporation of changes recommended by the Board. If COs sign decisional documents prior to submission to the Board and the Board directs changes, COs must include the changes as an addendum to the document.

c. If an OA submits a file for preaward review which was previously submitted for a presolicitation review, the cover memorandum should so indicate. The file must include the Minutes from the presolicitation review and the OA response to the Minutes.

9. The Chair will return files that lack essential documentation to the OA without a Board review. The files will not count toward the obligation under this Manual Chapter until they are resubmitted with complete documentation. Examples of this include those lacking an Acquisition Plan or lack of documented corrections to the file as a result of the OA internal review or an earlier Board review.

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I. SCOPE OF REVIEWS

1. The written review Minutes prepared by the Board will encompass the full scope of contracting considerations.

a. Substantive Issues

The Minutes identify substantive issues that the CO must resolve prior to proceeding. In general, substantive issues include, but are not limited to, the following types of problems:

(1) For presolicitation reviews –

-Statutory requirements or prohibitions overlooked or disregarded, e.g., lack of project concept review or applicable deferral; or failure to include the provisions pertaining to the Service Contract Act of 1965, as amended, when applicable;

-Evidence of faulty judgment on the part of the CO, e.g., when a contract is not the appropriate instrument; and

-Evaluation criteria that are not clearly stated or restrictive criteria that are not justified;

(2) For preaward reviews -

-The file documentation does not clearly justify source selection;

-Major clearances not obtained, such as the equal employment opportunity clearance;

-An award document that fails to reflect the essential agreement of the parties, e.g., when the contract document and the Final Proposal Revision are significantly different; and

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-A proposed contract lacks the required Small Business
Subcontracting plan with the CO's approval.

b. Advisory Issues

All issues raised by the Board, other than the Substantive Issues, are considered recommendations by the Board. Whenever possible, COs should resolve Advisory Issues and Other Matters prior to award.

c. Other Matters

These issues do not reflect upon the legal or regulatory sufficiency of an acquisition, but may reflect on the overall appearance and quality of the file. Therefore, these matters are brought to the attention of the CO for corrective action or for commendation.

2. Response to Board Minutes

a. Substantive Issues

During a presolicitation or preaward review, if the Board judges an issue as substantive, the Chair shall promptly notify the OA Director. The Chair will require the OA to resolve the substantive issue prior to the proposal due date or award of the contract. If appropriate, the OA will amend the RFP to resolve the substantive issue. The Chair shall provide a written addendum to the Minutes indicating resolution of the issue.

b. Advisory Issues

The OA Director shall respond to Minutes addressing resolution of Advisory Issues, within 30 working days from the date the Board issues its review. Note that responses to the Board must indicate the resolution of the issue. Board Minutes complete the cycle of an important management control for acquisition and, therefore, responses such as "noted" are not acceptable as they do not indicate how the OA resolved the matter.

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c. Other Matters

It is not necessary to respond to the Board about the disposition of "Other Matters." However, the OALM recommends that the CO correct minor issues, e.g., typographical errors, prior to the release of the document to the public.

J. RECORDS RETENTION AND DISPOSAL

Records Retention and Disposal: All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of the NIH Manual Chapter 1743, "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, Section 2600 Procurement, Property and Supply Management (all that apply) and Section 6000 Research Contracts (all that apply).

NIH E-Mail Messages: NIH e-mail messages (messages, including attachments that are created on the NIH computer systems or transmitted over the NIH networks) that are evidence of the activities of the agency or have informational value are Federal Records. These records must be maintained in accordance with current NIH Records Management Guidelines.

All e-mail messages are Government property, and if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, the 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 the Freedom of Information Act requests. As 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.

K. MANAGEMENT CONTROLS

This Manual Chapter establishes procedures for the submission of presolicitation and preaward contract files to the Board.

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1. **The Office Responsible for Reviewing Management Controls Relative to this Chapter:** OALM.
2. **Frequency of Review** (in years): OALM reviews percentages of new awards from each OA annually, based on the number of new awards during the previous three fiscal years. The Board reviews approximately ten percent of the new awards with a minimum of one file from each OA.
3. **Method of Review:** The Board conducts reviews and uses them to determine if acquisitions at the NIH are in compliance with the law and regulations. The Board conducts reviews in accordance with the FAR, the HHSAR, the NIH Manual Chapters, and other applicable policies and guidance.
4. **Review Reports:** DAPE sends reviews of individual presolicitation or preaward files to the appropriate OA for either immediate corrective action or remedial action within 30 days.