# **NIH Policy Manual**

## **6035 - Broad Agency Announcements**

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#### Transmittal Notice

1. **Explanation of Material Transmitted:** This manual chapter updates policy and guidance regarding Broad Agency Announcements (BAAs). This revision includes: policies on the use of white papers; pre-solicitation procedures; solicitation content requirements; and updated evaluation and debriefing requirements and procedures.

#### 2. Filing Instructions:

**Remove:** NIH Manual 6035 - dated 12/12/2001. **Insert:** NIH Manual 6035 - dated 05/11/2016.

#### **PLEASE NOTE:** For information on:

- Content of this chapter, contact the issuing office identified above.
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## A. Purpose

This Manual Chapter updates policy on the use of Broad Agency Announcements (BAA) at the National Institutes of Health (NIH). It incorporates best practices for use of the BAA for Federal Acquisition Regulation (FAR) procurements and expands the usage of the BAA as a mechanism for the NIH to achieve program objectives through transactions not subject to the FAR. The requirements of this manual chapter do not apply to the Small Business Innovation Research (SBIR) program.

#### **B.** Definitions

Broad Agency Announcement (BAA) – in addition to the definition found in FAR 2.101, a BAA is a method used by the NIH to solicit proposals for research and development projects. Under a BAA, the NIH may award a contract and any instrument it is authorized to use including but not limited to a grant, cooperative agreement or other transaction. The NIH shall only award the type(s) of instrument(s) stated in the announcement.

Proposal – A submission to the NIH in response to one or more areas of interest identified in a BAA, with an intent to enter into an agreement (e.g. contract, grant, cooperative agreement, other transaction or other instrument) with the NIH.

White Paper – A submission to the NIH in response to one or more areas of interest identified in a BAA. A white paper is often less detailed than a proposal and the NIH may request, but not require, the submission of white papers with a BAA. A white paper provides an opportunity for the NIH to obtain information from industry on R&D activities and capabilities, and to provide comments without the need to expend considerable time, money and other resources in preparing a full proposal. The NIH is not required to respond to a white paper (e.g. provide a debriefing).

## C. Background

The Federal Acquisition Regulation (FAR) 6.102(d)(2) establishes that the BAA is a competitive procedure that satisfies the Competition in Contracting Act of 1984 (CICA), 41 United States Code (U.S.C.) § 3301 et seq, requirement for full and open competition in the acquisition process.

The FAR 2.101 contains a definition of BAAs and 35.016 provides general procedures to be followed in using BAAs to award Research and Development (R&D) contracts subject to peer or scientific review (see FAR 6.102(d)(2)). The procedures below are in addition to those found in the aforementioned FAR citation and are unique to the NIH contracting community.

#### D. References

- 1. Competition in Contracting Act of 1984 (P.L. 98-369), as amended.
- 2. FAR 2.101, 6.102(d)(2), 19.201, and 35.016
- 3. NIH Manual Chapter 1743, Keeping and Destroying Records
- 4. NIH Manual Chapter 54110, Program Announcements and Requests for Applications
- 5. NIH Manual Chapter 6315-1, Review and Evaluation of R&D Contract Proposals
- 6. NIH Manual Chapter 6307-3, Special Clearance and Other Acquisition Procedures
- 7. NIH Manual Chapter 7410, Review and Documentation of Protections for Human Subjects in Extramural Grant Applications and Research and Development Contract Proposals
- 8. NIH Policy and Guidelines on the Inclusion of Women and Minorities as subjects in Clinical Research, amended 2001
- 9. NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects

### E. Policy

In some circumstances, in order to realize full and open competition and to fulfill requirements for scientific study and experimentation directed toward advancing the state-of-the-art, or increasing knowledge and/or understanding, the NIH will issue BAAs.

Acquisition and program officials shall collaborate in developing BAAs and making award decisions thereunder. Subject matter experts and other officials shall be involved as necessary.

At a minimum, the BAA shall solicit proposals for contracts. The BAA may also permit industry to submit proposals for grants, cooperative agreements, or other transactions or instruments. In choosing the appropriate award type, officials shall consider which type is best suited to achieve the goals of the R&D project. Officials shall comply with all applicable statutes, regulations, policies and procedures pertaining to the type of award required for the R&D project. The NIH is encouraged to utilize outreach programs with industry, such as industry days, requests for information, and pre-proposal conferences, among other things, to communicate and better inform industry of the NIH's areas of scientific interest. These outreach efforts also allow the NIH to remain informed of the latest developments within the area(s) of scientific interest.

#### F. Pre-solicitation Procedures

- 1. Planning: a project officer (or Contracting Officer's Representative or COR, as appropriate), in conjunction with a contracting officer and other relevant personnel shall prepare an acquisition plan and any other pre-solicitation documents as required by governing policies, regulations and statutes.
- 2. Concept Review: As with any NIH R&D contract project, the concept (basic purpose, scope and objectives) of each research area identified in a BAA shall undergo scientific peer review in accordance with statutes and implementing regulations at 42 U.S.C. § 289a, 42 Code of Federal Regulations (CFR) Part 52h,prior to issuing the BAA. The minutes of the advisory/peer review committee, in which the R&D concept was approved, shall be documented in the file.
- 3. Market Research: a BAA may serve as a method of additional market research and contracting officials are encouraged to use a BAA to request information (e.g. white papers) from industry to obtain a better understanding of their products and services as they relate to research and development programs. Contracting officials are encouraged, but not required, to provide feedback to third-parties that submit information in response to a BAA as market research. Use of a BAA for market research does not eliminate the need for the contracting officer and/or project officer to conduct preliminary market research prior to the issuance of the BAA.
- 4. Clearances: Contracting officers and/or project officers shall obtain whatever clearances are required prior to the issuance of the BAA. Contracting officers and/or project officers should ensure that any requirements for funding mechanisms other than FAR based contracts (e.g. cooperative agreements, grants, other transactions) comply with all applicable statutes, regulations and policies. See also: NIH Manual 6307-3, Special Clearance and Other Acquisition Procedures.

#### **G.** Solicitation Content

1. Format: A contracting officer is responsible for issuing the BAA. Unless otherwise required, contracting officers need not employ the Uniform Contract Format as

prescribed in FAR 15.204 and applicable HHS acquisitions regulations in formatting the content of the BAA. At a minimum, the BAA shall include all information required by FAR Subpart 35.016 and a description of the following:

- a. Issuing Office and Point of Contact for Submissions;
- b. Programmatic Background;
- c. Area(s) of Interest;
- d. Standard award reporting requirements, if any;
- e. Standard award terms and conditions, if any;
- f. Representations and Certifications, if any;
- g. White Paper and/or Proposal Instructions;
- h. White Paper and/or Proposal Due Date(s);
- i. Award Type(s) and Notice of any Small Business Set Aside(s);
- j. Anticipated Award Date(s), and;
- k. Evaluation Criteria.
- 2. Area(s) of Interest: the BAA shall describe areas of scientific or research and development interest. The BAA should request a statement of work or work plan for the proposed research project.
- 3. Period for Accepting Proposals: Proposals may be accepted for evaluation under a BAA for a period not to exceed three years from the date the BAA is published on the Government Point of Entry (GPE). Proposal revisions may be accepted to any proposal initially received within the three year period.
- 4. Award Type: The BAA shall contain a statement that contract awards are anticipated. The BAA may also contain a statement regarding whether other award type(s) (e.g. grant, cooperative agreement or other transaction) are permitted. The BAA shall also state the estimated period of performance and whether one or more awards are anticipated.
- 5. Evaluation Criteria: The BAA shall state the criteria for selecting a proposal for award. The evaluation criteria shall describe their relative importance and method of evaluation. Typically, the criteria for selecting proposals for a contract award under a BAA include technical, importance to NIH's programs, cost/price, fund availability and where applicable, past performance, and mandatory criteria or special considerations (e.g. human subjects research, animal research, select agents/toxins/highly pathogenic materials, and controlled substances or narcotics see also NIH Manual Chapters 6315-1 and 7410 for additional information). Other relevant factors may be considered.
  - a. The BAA shall clearly state the technical evaluation criteria. Such criteria may, but are not required to, include:
    - i. Overall feasibility of the proposed project.
    - ii. Adequacy and relevance of the proposed research plan.
    - iii. Capabilities, related experience, facilities, and techniques, which the offeror possesses (and which are considered integral factors) for achieving the objective.

- iv. Qualifications, capabilities, experience, and availability of proposed key personnel.
- b. The NIH may request, with an initial proposal, a rough order of magnitude price/cost estimate in lieu of a detailed cost proposal. If cost analysis is required or employed, the contracting officer shall obtain a detailed cost proposal prior to a source selection decision.
- c. Past performance must be included as an evaluation factor in all acquisitions expected to exceed the simplified acquisition threshold unless the contracting officer documents the reason(s) why past performance is not considered an appropriate evaluation factor for the acquisition.
- 6. Publication: in addition to the procedures found at FAR 35.016, a BAA should be published in the NIH Guide to Grants and Contracts and the GPE, in order to reach as many organizations as possible. In accordance with FAR 35.016(c), if the published notice of a BAA is a general notice of ongoing research opportunities, it shall be published no less frequently than annually to reach the broadest possible audience. FAR 35.016(f) provides that synopsis of individual contract actions based on proposals received under the BAA is not required since the notice requirements of FAR 35.016(c) satisfy the publication requirement of FAR 5.2.

## H. White Paper Review

- 1. If the BAA permits the submission of white papers, subject matter experts with relevant knowledge of the third-party's R&D activities and capabilities should review the white papers and provide comments to the COR and the contracting officer. NIH program offices should establish internal processes and procedures to review white papers. White papers are not required to undergo scientific peer review as described 42 USC § 289a, 42 CFR Part 52h, and NIH Manual Chapters 6315-1 and 7410.
- 2. The NIH is encouraged to respond to white paper submissions with an indication as to whether the NIH is interested in receiving a proposal for an R&D project based on the activities and capabilities described in the white paper. The NIH may also provide comments on white papers to third-parties that submitted them. If the NIH informs a third-party that it is interested in receiving a proposal, the NIH should advise that submission of a proposal under a BAA does not guarantee an award.

## I. Proposal Evaluation

1. The proposals received in response to a BAA shall be evaluated by the peer review process as established at 42 U.S.C. § 289a, 42 CFR Part 52h, NIH Manual Chapters 6315-1 and 7410 and in accordance with the established technical evaluation criteria in the BAA. Minimally, a written technical evaluation report (TER), prepared by a Scientific Review Officer, describing the offeror's strengths and weaknesses, assessing the scientific merit and making overall recommendations as to the acceptability or unacceptability shall be prepared. The TER is based on the proposal's technical merit as related to the evaluation criteria stated by the government for the area on which the

- organization has chosen to submit a proposal. Relevant mandatory criteria may be evaluated during the peer review process as appropriate. The TER shall be documented in the file.
- 2. Cost realism and cost/price reasonableness shall also be considered to the extent appropriate. For awards subject to the FAR, certified cost and pricing data is required if the total price of the contract exceeds \$700,000. Where applicable, past performance and any other criteria included in the solicitation shall also be evaluated. Award documents will be tailored to the final negotiation with the selected offeror(s) and modified as appropriate for the type of organization, cost and/or fee arrangement, and other elements as negotiated prior to the award.
- 3. Awards may be made with or without discussions. As proposals submitted under a BAA offer unique approaches to generally described areas of interest, use of competitive range determinations does not typically occur prior to source selection decisions. Rather, proposals should be evaluated independently and source selection decisions based on the criteria described in the BAA. For award types not governed by the FAR (e.g. cooperative agreements, grants and other transactions), applicable statutes, regulations and policies shall be followed. The awards will be subject to fund availability and the priority that the Institute/Center (IC) determines to exist at the time of award.
- 4. If a proposal is not selected for award, the IC shall provide a written notice to the unsuccessful party. If the unsuccessful party proposed an award type subject to the FAR, the unsuccessful party is entitled to a debriefing if the Contracting Officer or the point of contact, as stated in the BAA, receives a written request for a debriefing within 3 days after receipt of the notice that its proposal was not selected for award. For award types not subject to the FAR, the requirement for a debriefing or an equivalent shall depend on the relevant statutes, regulations and policies governing those award types.
  - a. For award types subject to the FAR:
    - i. If an unsuccessful party timely requests a debriefing of a proposal, the IC shall decide what method to provide it and to the maximum extent practicable, provide the debriefing within 5 days after receipt of the written request.
  - b. The content of the debriefing shall include at a minimum:
    - i. evaluation of significant elements in the proposal;
    - ii. summary of the rationale for not selecting the proposal for award, and;
    - iii. reasonable responses to relevant questions about whether award procedures contained in the BAA, applicable regulations, and other applicable authorities were followed in the process of not selecting the proposal for award.
  - c. The debriefing shall not include or disclose:
    - i. the number of proposals submitted to the BAA;
    - ii. the identity of other parties;

- iii. the content of other proposals;
- iv. the ranking of other proposals;
- v. the evaluation of other proposals;
- vi. point-by-point comparisons of the debriefed proposal with those of other proposals;
- vii. any information prohibited by FAR Subpart 24.2 (Freedom of Information Act) as applicable, and;
- viii. any information exempt from release under the Freedom of Information Act including trade secrets, privileged or confidential manufacturing processes and techniques, commercial and financial information that is privileged or confidential (including cost breakdowns, profit, indirect cost rates and similar information), and the names of individuals providing reference information about a proposer's past performance.

## J. Records Retention and Disposal

All records 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 Schedules" (as amended). These records must be maintained in accordance with current NIH Records Management and Federal guidelines. Contact your IC Records Liaison or the NIH Records Officer for additional information.

#### K. Internal Controls

The purpose of this Manual Issuance is to provide updated guidance to contracting officers and program officials on the statutes, regulations, policies and procedures regarding BAAs.

- 1. Office Responsible for Reviewing Management Controls Relative to this Chapter: The Division of Acquisition Policy and Evaluation, Office of Acquisition Management and Policy, Office of Acquisition and Logistics Management, Office of Management, Office of the Director (DAPE/OAMP/OALM/OM/OD).
- 2. Frequency of Review: On-going review.
- 3. **Method of Review:** The DAPE/OAMP/OALM will maintain appropriate oversight through reviews of the Offices of Acquisition (OA) pre-award contract files conducted by the NIH Board of Contract Awards. The NIH Board of Contract Awards reviews a percentage of contract actions from each OA. Issues identified by the NIH Board of Contract Awards are provided to the OA for corrective action. When repetitive issues are identified, DAPE brings them 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 implementation of policy by DAPE and OAs. 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. <b>Reports:</b> Year-End Summary Report of Repetitive Issues will be sent to the Directors, OA and to the Deputy Director for Management, and will be posted on the DAPE website.