

NIH POLICY MANUAL

6315-3 - TECHNICAL EVALUATION OF PROPOSALS SUBMITTED IN RESPONSE TO SBIR CONTRACT SOLICITATIONS

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1. **Explanation of Material Transmitted:** This chapter is being issued to implement applicable portions of 15 U.S.C. 638 (P.L. 97-219), as amended, entitled "Small Business Innovation Research (SBIR) Program." It also incorporates coverage pertaining to the submission of requisite certifications prescribed under current procurement integrity, conflict of interest, and confidentiality of information policies and procedures. By this issuance, I&I Memorandum DCG 84-31 (Rev. 1) is superseded.
2. **Filing Instructions:**
 - Remove:** I&I Memorandum DCG 84-31 (Rev. 1), dated 4/17/91
 - Insert:** NIH Manual 6315-3, dated 7/20/94
3. **Distribution:** NIH Mailing Keys F-401, F-402, F-404, F-407

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- content of this chapter, contact the Division of Acquisition Policy and Evaluation, OCM, OA, on (301) 496-6014.
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A. Purpose:

This issuance implements applicable portions of 15 U.S.C. 638 (P.L. 97-219, Small Business Innovation Development Act of 1982), Small Business Innovation Research (SBIR) Program, Policy Directive No. 65-01, pertaining to technical evaluation of the SBIR contract proposals, and Public Law 102-564, Small Business Research and Development Enhancement Act of 1992. In addition, this issuance incorporates coverage pertaining to the submission of requisite certifications prescribed under current procurement integrity, conflict of interest, and confidentiality of information policies and procedures.

B. Background:

P.L. 97-219, as amended, has the broad objective of stimulating small business participation in Federal Research and Development (R&D) extramural projects and increasing private-sector commercialization of technological innovations derived from performance of such projects. The SBIR Program, Policy Directive No. 65-01, as amended, entitled "Small Business Innovation Research Program," implements P.L. 97-219 and provides general guidance on the conduct of the SBIR Program.

Both P.L. 97-219 and the SBIR Program Policy, Directive No. 65-01, emphasize that simplified procedures should be developed and existing regulations should be streamlined to facilitate the process of obtaining research and development from small business concerns. The SBIR Program Policy Directive, published in the Federal Register on January 26, 1993 (58 FR 6144-6155) provides updated guidance reflecting new statutory requirements for the SBIR Program.

C. Policy:

By implementation of P.L. 97-219, and by its further amendments, agencies of the Public Health Service, HHS, are required to set aside a specified amount of their (R&D) budgets for a SBIR Program. This program has among its purposes the stimulation of technological innovation, the use of small business to meet Federal R&D needs, the increase of private sector commercialization of innovations derived from Federal R&D, and the fostering and encouragement of participation by minority and disadvantaged persons in technological innovation.

Agencies are encouraged to use their own established review processes for the review of the SBIR proposals. The SBIR legislation authorizes peer evaluation when appropriate. Peer evaluation of biomedical and behavioral research proposals is mandated for the NIH by the PHS Act, Sections 405(b)(2)(A) and 492(a), and 42 CFR 52h.

D. References:

1. 15 U.S.C. 638 (P.L. 97-219), Small Business Innovation Development Act of 1982.
2. Small Business Innovation Research (SBIR) Program, Policy Directive No. 65-01, as amended, January 8, 1985.
3. PHS Act, as amended, December 31, 1987, Sections 405 and 492.
4. 42 CFR Part 52h, PHS Scientific Peer Review of Research Grant Applications and Research and Development (R&D) Contract Proposals.
5. P.L. 102-564, Small Business Research and Development Enhancement Act of 1992.
6. SBIR Program Policy Directive, published in the Federal Register January 26, 1993.
7. NIH Manual Chapter [6315-1](#), Review, Evaluation, and Award of R&D Contract

Projects.

8. I&I Memorandum OD 90-1, Conflicts of Interest and Confidentiality Certifications for Evaluations of Grant and Cooperative Agreement Applications, Contract and Subcontract Proposals, and Active Projects.

9. I&I Memorandum OER 91-1/DCG 91-2, Procurement Integrity Act, Conflict of Interest, and Confidentiality Certification Implications for Individuals Evaluating the Scientific and Technical Merit of the NIH Contract Proposals (1805/6315-1/26315-1).

10. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, March 9, 1994 (published in the Federal Register on March 28, 1994. (59 FR 14508-14513).

E. Procedures:

1. The Institutes, Centers and Divisions (ICDs) sponsoring the SBIR contract projects shall manage the evaluation process for their SBIR proposals. Accordingly, no central NIH activity (such as the Division of Research Grants) is designated to receive and evaluate the SBIR proposals.
2. The SBIR solicitations encourage potential offerors to submit proposals on topics or in areas of special interest to the sponsoring ICD program activity that cannot be defined in detail, but can be described in terms of program aims and objectives.
3. Lead time for receipt, technical evaluation, and award of the SBIR contracts shall be six months or less, consistent with the objectives of the program.
4. All the SBIR project concepts shall be reviewed by a scientific peer review group in accordance with the provisions contained in the NIH Manual Chapter [6315-1](#).
5. The PHS SBIR Program solicitation shall be prepared and issued by the SBIR Program Coordinator, Office of Extramural Programs, NIH, in accordance with Appendix 1 of the SBIR Program Policy Directive.
6. As provided in the SBIR solicitation, contract proposals are submitted by offerors to the contracting officer identified with the ICD research topic area. After determining that the technical and business portions of proposals received are complete in all respects, and identified with one of the topic areas in the SBIR solicitation, the contracting officer shall forward all proposals (technical portion together with direct cost information), to the ICD review office/staff.
7. The SBIR contract proposals shall be evaluated by a Technical Evaluation Group (TEG) competent to make judgments about the proposals submitted in the SBIR topic area. The TEG shall consist of at least seventy-five percent non-Federal scientists and/or technical experts. In order to provide appropriate balance to the membership of the TEG, one or more representatives from the small business community who are knowledgeable about the topic area, should be included. The task of the TEG will be to evaluate proposals in accordance with the technical evaluation criteria announced in the SBIR solicitation, and

to perform a concept review if one was not accomplished previously.

8. Responsibility for establishing TEGs, conducting evaluation meetings, and preparing evaluation reports is that of the Scientific Review Administrator (SRA) of the ICD Scientific Review Office/Component.
9. The SRA shall ensure that the requisite conflict of interest/confidentiality of information and procurement integrity certifications are obtained from the TEG members prior to commencement of the scientific or technical merit evaluations.
10. Before TEG members begin the task of evaluating proposals, the SRA should orient the TEG on the SBIR Program objectives. Program staff may address the TEG on background information on specific topic areas. A member of the contracting staff should brief the TEG on the competitive distinctions between conventional contract proposals and the SBIR proposals. The SRA should further brief the TEG on differences in the review processes between conventional and SBIR proposals. It should be emphasized that a conventional contract project involves a Statement of Work developed by the Government, whereas an SBIR project involves work requirements developed and defined by the SBIR offeror. Therefore, an SBIR project involves a competition of ideas and approaches toward fulfilling program objectives and solving priority technological problems. At the same time, it can be expected that the SBIR contractor will conduct research that will yield the contractor a profit and that may lead to the development of a product or process with commercial potential. As there is no multiple-source competition for a single acquisition objective defined by the Government, it should be explained to reviewers that the SBIR contract projects do not require establishing a competitive range or making calls for best and final offers before reaching source selection decisions.
11. Utilizing the evaluation criteria specified in the SBIR solicitation, the TEG shall rate and make overall recommendations as to the acceptability and unacceptability of all proposals reviewed. Rating proposals by the TEG should be on the basis of a simple point scale. Complicated rating techniques should be avoided in the SBIR Program.
12. A second-level review may also be made by the program staff of the awarding component. The second-level review confirms proposal strengths and weaknesses noted in the technical evaluation summaries and if applicable, identifies any additional proposal ambiguities, inconsistencies, deficiencies, errors, and other program-based issues. In making award recommendations, the program staff shall take into consideration the following: (a) ratings resulting from the scientific/technical review process; (b) areas of high-program relevance; (c) program balance (e.g., balance among areas of research); and (d) available funds. In general, the highest-rated proposal(s) in each topic area should be selected for award if conditions stated in (a) through (d) are satisfied.
13. Recommendations of the evaluating group and program staff are based primarily on scientific and technical merits, and potential contributions of the offeror's proposed research to the mission and programs of the awarding component. Awarding components may award a contract only if a proposal is technically acceptable. However, acceptable proposals are not automatically funded. In any case, unless award without discussions is clearly indicated, preaward technical discussions and negotiations take place with

offerors recommended for award.

14. The SBIR documentation shall reflect a clear rationale for the technical rating, actions on recommendations of the TEG and the program staff, and a clear and supportable basis for the source-selection decision(s) made by the contracting officer.
15. After final award decisions have been announced, the contracting officer shall provide a debriefing to any offeror who submits a written request.
16. Unlike direct competition for a single acquisition objective under a conventional contract solicitation, the contracting officer or negotiator has more flexibility negotiating SBIR projects. For example, within the framework of SBIR rules and procedures, program may recommend scaling up or scaling down individual SBIR proposals in terms or cost or scope without risk of prejudicing the competitive interests of other SBIR offerors. However, the degree of scaling up or scaling down, or program's desire to make other realignments in a proposal, shall not be of such magnitude as to invalidate the technical evaluation of the original proposal. Otherwise, another evaluation and rescoring may be required. In instances where the SBIR offerors are requested to submit revisions to proposals that are not of a significant nature, the new evaluation and rescoring may be accomplished by program staff.

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