

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

COMMITTEE AND CONFERENCE MANAGEMENT

FDA SCIENTIFIC REVIEW OF RESEARCH AND DEVELOPMENT PROJECTS

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1. Purpose
2. Definitions
3. Establishment and Composition of Scientific Review Groups
4. Conflict of Interest
5. Scientific Review of Research and Development Contracts
6. Procedure

**1. PURPOSE**

This guide prescribes the FDA policies and procedures for the review of research and development contract projects by scientific review groups.

**2. DEFINITIONS**

- A. Research. A systematic, intensive study directed toward fuller scientific knowledge or understanding of the subject studied. Research may be classified as either basic or applied.
1. Basic Research. The investigator is concerned primarily with gaining a fuller knowledge or understanding of the subject under study.
  2. Applied Research. The investigator is primarily interested in a practical use of the knowledge or understanding for the purpose of meeting a recognized need.
- B. Development. A systematic use of the knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes. It excludes product testing, inspections, regulatory investigations, quality control, training, and data collection and the development of a specific piece of equipment whose working prototype already exists.

- C. Scientific Support. A service dealing with scientific subject matter, but not involving the conduct of either research or development.
- D. Scientific Review Group. A group of experts qualified by training and experience in particular scientific and technical fields, assemble for the purpose of reviewing specific research and development contract projects and advising the FDA at an early point in the Agency approval process as to the scientific and technical merit of the project.
- E. Memorandum of Need (MON). The Memorandum of Need (MON) contains the sponsor's authorization to obligate funds, provides administrative details essential to the development of a Request For Proposal (RFP), and serves as the official requisitioning document for basic or sup-porting services of a medical or scientific nature.
- F. Bureau. As used in this Staff Manual Guide, includes EDRO and components of the Office of the Commissioner.

### **3. ESTABLISHMENT AND COMPOSITION OF SCIENTIFIC REVIEW GROUPS**

- A. Each bureau director and the Director, NCTR shall establish, within their organization, a scientific review group for each research and development contract. In the case of competitive contract projects, this group may be established by augmenting the membership of the Project Advisory Group. This group may include bureau personnel, personnel from other parts of the Federal Government, and personnel from outside the Federal Government. The group shall include at least 50 percent non-FDA employees, and a reasonable effort should be made to include at least one non-Federal employee. On occasions where it is necessary to utilize a scientist who is not a special Government employee of the FDA, and where the use of the particular scientist is anticipated to be infrequent (not more than one to three times a year), the bureau may wish to obtain the services of the scientist by Professional Services Contract. This involves a non-stock requisition HEW Form 393, as provided for under SMG FDA 2610.7. (Each requisition should include necessary travel, per diem, and appropriate remuneration even if more than one trip is approved.)
- B. In the establishment of the scientific review group, the bureau or NCTR may use an existing PAG or members thereof provided the makeup of the existing committee is consistent with the requirements described above. The bureaus or NCTR may consult with the Office of Science to obtain potential nominees as they consider necessary.

- C. Members shall be selected based on their training and experience in relevant scientific or technical fields, taking into account, among other factors:
1. The level of formal scientific or technical education (e.g., B.S., M.A., Ph.D., M.D.) completed by the individual;
  2. The extent to which the individual has engaged in relevant research;
  3. Professional stature as reflected by position, memberships, and other recognition from scientific and Professional organizations; and
  4. The need of the group to include within its membership experts from various areas of specialization within relevant scientific or technical fields.

#### **4. CONFLICT OF INTEREST**

- A. Members of scientific review groups covered by this Guide are subject to relevant provisions of Title 18 of the United States Code, relating to criminal activity, the DHEW Standards of Conduct (45 CFR Part 72), Executive Order 11222, as amended, and the FDA Supplement to the HEW Standards of Conduct. Any questions in regard to conflict of interest should be coordinated with the Conflict of Interest Staff (HFA-25).
- B. In addition to any restrictions imposed under paragraph a., above, no member of a scientific review group shall participate in or be present during any review by said group of a contract proposal submitted in response to an RFP by an organization in which the member, his or her spouse, parent, child, or partner has a financial interest, or is serving as an officer, director, trustee, partner, or employee or is negotiating any arrangement concerning prospective employment.
- C. In the event any member of a scientific review group, or his or her spouse, parent, child, or partner is currently or expected to be the principal investigator or member of the staff responsible for carrying out any research or development activities contemplated as part of a particular MON, or contract proposal, the member shall be excused from the review.
- D. Where a member of a scientific review group participates in, or is present during, development or review of an MON (project approach) or contract proposals (after the issuance of a Request For Proposals (RFP)), no contract for that project may thereafter be awarded to the member, his or her spouse, parent, child, or partner or any organization with which the member is associated.

## 5. SCIENTIFIC REVIEW OF RESEARCH AND DEVELOPMENT CONTRACTS

- A. Each new research and development contract project and Interagency Agreement for which FDA provides monies to other parts of the Federal Government to have R & D accomplished, of \$50,000 or more per annum, shall be reviewed for scientific merit by the initiating bureau's/ NCTR's scientific review group established for that project prior to forwarding of the MON to the Associate Commissioner for Science.
- B. Each renewal, incrementally funded contract, and modified active contract of \$50,000 or more shall also be subject to review by the appropriate scientific review group, when in the opinion of the bureau/NCTR, there is a significant change in the scope of work or dollar amount prior to submission of the MON to the Associate Commissioner for Science. In any event, all active research and development contracts of \$50,000 or more per annum shall be subject to a scientific review by the appropriate scientific review group at least once every three years. Annually the Office of Science and the Office of Administration will review the \$50,000 limit in light of inflation and constant dollars.
- C. In the case of all noncompetitive contracts subject to the scientific review requirement, review shall include the MON as well as the contract proposal. If the latter is available prior to forwarding the MON to the Associate Commissioner for Science, the review of the two documents should be conducted simultaneously.
- D. Individual bureaus and NCTR are responsible for determining which of their proposed projects are for research and development and shall be subject to scientific review. Such determinations are subject to review by the Associate Commissioner for Science, who shall have the right to request such a review or to request further review of inadequate reviews before approving a specific MON. The source of funding for a project (i.e., operating funds or project contract funds) has no bearing on whether or not a proposed project is subject to scientific review.
- E. Scientific support projects, as well as research and development projects, below \$50,000 per annum shall not require review by a scientific review group, but may receive such a review if the bureau/ NCTR so desires.
- F. The review by the scientific review group shall only be advisory to the bureau/NCTR and shall only cover scientific and technical merit; and shall not assess a proposed project's relevance, need, or priority to the bureau/NCTR. If the bureau/NCTR should decide to proceed with a contract project which has received an unfavorable evaluation by a scientific review group, their reasons must be fully documented in the appropriate file.

- G. The scientific review required herein may be waived by the bureau/NCTR in certain instances; e.g., the urgency of a project, the confidential nature of the material that would be subject to review, or the nonavailability of an appropriately qualified non-FDA reviewer. When this exemption is used, it shall be documented and subject to review by the Office of Science.

## **6. PROCEDURE**

- A. Each bureau/NCTR shall insure that a scientific review is conducted by the appropriate scientific review group for all applicable contract or Interagency Agreement MONs and for those proposals determined to be in the competitive range, all active contracts, and all noncompetitive MONs and proposals as required by paragraphs 5. a., b., and c., above.
- B. The scientific review group may or may not meet as a body to satisfy the requirements for scientific review. In the event they do not meet as a body, each member of the scientific review group shall submit a written evaluation of the project to the project officer. If they do meet as a body, their joint review shall be documented.
- C. After receipt of the reviews on all new MONs and noncompetitive MONs and proposals, the project officer shall attach the reviews to the specific MON and process it in accordance with Staff Manual Guide 2610.1.
- D. The scientific reviews prior to award of new competitive proposals required by paragraph 6. a. above, should be accomplished by the expanded Project Advisory Group as indicated in paragraph 3. a. This review should be based on the criteria set forth in the specific RFP and documented in accordance with current procurement procedures. When the bureau/NCTR elects to use a scientific review group, separate from the PAG, for new competitive contracts, the reviews should be coordinated with the Division of Contracts and Grants Management in order to avoid problems in the procurement process.