NIH Policy Manual

1805 - Use of Advisors in Program and Project Review and Management

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Transmittal Notice

A. Purpose

This manual issuance describes NIH policies and procedures for the use of advisors in the initiation, management, and evaluation of extramural programs and projects.

B. References

1. Code of Federal Regulations, Title 42, Part 52h -Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects.
2. Code of Federal Regulations, Title 45, Part 11 - Committee Management.
3. NIH Manual 1141 – Selection and Appointment of Members of Public Advisory Boards and Committees.
4. NIH Manual 1831 – Extramural Project Initiation by NIH.
5. NIH Manual 4510 – Referral and Initial Review of NIH Grant and Cooperative Agreement Applications (Rescinded).
6. NIH Manual 54511* – Project Site Visits Involving Review of Grant and Cooperative Agreement Applications (Rescinded).
7. NIH Manual 54513* – Review of NIH Programs and Grant and Cooperative Agreements Applications by National Advisory Councils and Boards.
8. NIH Manual 2300-735-2 – Procedures for Avoiding Conflict of Interest for Public Advisory Committee members.
9. NIH Manual 6000–303.51 – Review and Evaluation of R&D Contract Proposals.
10. NIH Committee Management Handbook.

C. Responsibilities

1. Office of the Director, NIH

    a. The Associate Director for Extramural Research and Training (ADERT), NIH, establishes policies and determines the adequacy of the mechanisms utilized to

obtain advice for NIH programs.

b. The ADERT, NIH, monitors, both on a continuing basis and as part of annual program reviews, the BID practices for carrying out established policies and procedures governing the use of program advisors.

2. Bureau/Institute/Division

a. BID Directors define the principles and procedures to be followed by program and review staffs in obtaining advice for each program within the framework of the policies set forth herein.

b. BID program and review managers are responsible for proposing the types of advisors, identifying the points at which advice will be sought for each program and project, and following the policies and procedures established by NIH and BID Directors.

D. Definitions

1. Advisors are primarily nongovernment scientists or other technical persons expert in subject matter areas relevant to a program, and who review, evaluate, and recommend regarding pertinent aspects of the program. They may also be government scientists or other technical personnel employed elsewhere than in the specific program area in which their advice is sought, or nongovernment business or lay persons with knowledge and interest in the program, e.g., public members of National Advisory Councils and Boards. Advisors participate principally as members of NIH advisory committees (e.g., National Advisory Councils and Boards, chartered BID advisory committees, DRG study sections), as participants in ad hoc review groups, and occasionally as individual consultants.
2. Advisory group is a collection of advisors whose views are assembled to accomplish advisory functions as in D.1., above. The term includes any subgroups of advisory groups, who provide their recommendations directly to appropriate officials of HHS or NIH.
3. Advisory group meeting is a gathering of advisors to bring together and to discuss their reviews, opinions, and recommendations.
4. Immediate family of advisors are their spouses, parents, and children.
5. Close associates of advisors are their coworkers, and other colleagues with whom they regularly coauthor papers, consult, or otherwise closely relate.
6. Advisor’s or other person’s organization is an institution, partnership corporation, agency, or similar entity with which that advisor or person is currently associated or is negotiating or has an arrangement for prospective association as employee, officer, director, partner, trustee, or consultant; has an appointment or professional privilege; or has any other financial or significant professional interest. All locations, campuses, and divisions of an organization are regarded as a single entity.
7. Ad hoc review is NIH use of advisors as individuals or groups for a single delimited review purpose or task and not on a continuing basis.
8. For definitions of program, project, RFA, and RFP, see NIH Manual 1831.

E. Policy

It is NIH policy to obtain the most competent advice for management of its programs and projects. Advisory group members are chosen from among those individuals best qualified as to their experience, capability, and recognized achievement in relevant fields; their mature judgment and objectivity; and their ability and availability to participate adequately in the advisory group structure. Please note that the race, ethnicity, sex, or disability status of an individual will not be considered when selecting advisory group members. Every effort is made to avoid both the fact and the appearance of conflict of interest in obtaining program advice.

The roles of advisors are critical to effective program management, but their activities are advisory only and do not supersede the responsibilities of Federal executives who are responsible and accountable for the management of those programs.

F. Guidelines for Use of Advisors

BID program managers regularly seek the advice of experts from outside the program staff regarding:

- planning and evaluation of program activities
- initiation of projects employing the contract mechanism, e.g., review of concepts of proposed projects for scientific merit and program priority before preparation and publication of RFPs;
- initiation of projects employing the grant and cooperative agreement (CA) mechanisms, e.g., review of program plans leading to proposed RFAs;
- technical evaluation of contract proposals--generally performed by BID contract review committees, but may be performed by other established committees such as study sections or by ad hoc groups;
- technical merit review of grant and CA applications--performed by study sections or BID initial review groups or by ad hoc groups;
- program priority review of grant and CA applications--performed by National Advisory Councils or Boards; and
- monitoring and evaluation of ongoing projects and programs.

1. Advisory Group Membership

    a. No more than one member may be appointed to an advisory group from the same institution, but geographically separate campuses within a multicampus university system or separate locations of a corporation may be considered to be separate entities for this purpose. If a member of an advisory group changes employment affiliation to that of another member, the ADERT, NIH, shall be consulted to determine whether it is appropriate to continue the term of the member who moved. In the event of unresolved disagreements, the Director,

NIH, shall make the final determination.

b. BID staff are ineligible to participate as members or executive secretaries of scientific or technical review groups in evaluating and recommending on specific grant applications, contract proposals, or projects for which they have had or may have other selection, award, or administration responsibilities. They should attend meetings of review and evaluation groups recommending on applications, proposals or projects within their responsibilities, so that they may provide technical, administrative, and program information essential for adequate review and evaluation. They may not, however, join in the scientific-technical-administrative discussions, evaluations, or recommendations of the review groups concerning those projects or proposals.

2. Conflicts of Interest

Program, review, and business management staff must be continually sensitive to the fact that advisors in various phases of program operations might, in certain instances, obtain competitive advantages if they or their immediate families, close associates, or organizations submit grant applications or contract proposals in program areas where they act as advisors. Staff must seek to avoid both the fact and the appearance of conflict of interest involving advisors. As general policy to avoid the fact or appearance of conflict of interest, advisors are disqualified from performing duties or rendering advice which might have a direct and predictable effect on the interests of individuals or organizations with which they are closely related or affiliated (see D.4.,5., and 6.). Specifically:

a. Advisors must absent themselves from portions of meetings during the review or evaluation of:

   i. the technical merit or program priority of specific grant applications or noncompetitive contract proposals in which they, their immediate families or close associates, or their organizations have a financial interest, even if these persons have no significant involvement.
   ii. the interim status of active projects in which they, their close associates, immediate families, or organizations are involved; advisors must be absent from the entire portions of such meetings when those projects are evaluated along with others being considered for designated funds.

b. Advisors are ineligible to attend or participate in meetings during the technical evaluation of competitive contract proposals which are from their immediate families, close associates, or their organizations, or which compete in response to the same RFPs.

c. Advisory groups are disqualified from reviewing grant applications, contract projects, or contract proposals which name members of those groups or their close associates or immediate families as principal investigators or other staff primarily responsible for conducting the planned research or development activities described.

i. Any reviews of those applications, proposals, or projects must be conducted by other group(s) with the necessary expertise.
ii. No more than fifty percent of the members of any ad hoc group(s) selected for those reviews may be from the disqualified group(s).

d. Advisors, their immediate families and close associates, and their organizations are ineligible to receive contract awards resulting from RFPs for which those advisors have participated in the development or review of the project approaches or RFPs.
e. An individual who has acted or is negotiating to act as a consultant to an institution or organization for a specific application, proposal, or project may not serve as an advisor to NIH during any stage of NIH review of that application, proposal, or project. If the advisor is a member of a review group evaluating the application, proposal, or project, the advisor must be absent from that portion of the meeting in which it is being discussed. (See also 2.b. for restrictions on evaluation of competitive contract proposals.)
f. Advisors may not discuss with NIH extramural staff matters pertaining to their institutions' federally funded activities, during a meeting of the review group on which the advisor is serving.

3. Special Exemptions

a. Where legally permissible, the Director, NIH, or designee, after review of adequate written justification submitted by a BID Director, may waive the requirements above in specific instances after determining that their application would preclude attainment of adequate scientific, technical, or program advice. The BID Director must explain fully the circumstances for the suggested deviation and must obtain advance written approval for the deviation (see, e.g., 42 CFR 52h.5(c)).
b. When program advisors have participated in presolicitation review and are likely to be among those submitting proposals or applications (after waiver as described in a., above, when necessary), the period between publication of the announcement and the deadline for responses will be longer than normal, e.g., extended by an additional 30 days.

G. Additional Information

For further information contact OERT/OD, 301-496-2241.

H. Additional Copies of Manual Chapters

For copies of this manual chapter send a memorandum to the Printing and Reproduction Branch (P&RB), DAS, in Building 31, Room B3BE07; or call OERT/OD, 301-496-2241.