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Administrator requires. The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the PHS Act and the Social Security Act, as pertinent, the regulations of this subpart, and any additional terms or conditions of any grant awarded.

(b) In addition to information requested on the application form, the applicant must provide such other information as the Administrator may request.

§67.15 Peer review of applications.

(a) *General procedures for peer review.* (1) All applications for support under this subpart will be submitted by the Administrator for review to a peer review group, in accordance with section 922(a) of the PHS Act, except that applications eligible for review under section 922(d)(2) of the PHS Act (''small grants'') may be reviewed under adjusted procedures in accordance with paragraph (b) of this section.

(2) Members of the peer review group will be selected based upon their training and experience in relevant scientific and technical fields, taking into account, among other factors:

(i) The level of formal education (e.g., M.A., Ph.D., M.D., D.N.Sc.) completed by the individual and/or the individual's pertinent experience and expertise;

(ii) The extent to which the individual has engaged in relevant research, the capacities (e.g., principal investigator, assistant) in which the individual has done so, and the quality of such research;

(iii) The extent of the professional recognition received by the individual as reflected by awards and other honors received from scientific and professional organizations outside the Department of Health and Human Services;

(iv) The need of the peer review group to include within its membership experts representing various areas of specialization within relevant scientific and technical fields, or specific health care issues; and

(v) Appropriate representation based on gender, racial/ethnic origin, and geography.

(3) Review by the peer review group under paragraph (a) of this section is conducted by using the criteria set out in paragraph (c) of this section.

(4) The peer review group to which an application has been submitted under paragraph (a) of this section shall make a written report to the Administrator on each application, which shall contain the following parts:

(i) The first part of the report shall consist of a factual summary of the proposed project, including a description of its purpose, scientific approach, location, and total budget.

(ii) The second part of the report shall address the scientific and technical merit of the proposed project with a critique of the proposed project with regard to the factors described in paragraphs (c)(1)(i) through (c)(1)(x) or (c)(2)(i) through (c)(2)(vii) of this section as applicable. This portion of the report shall include a set of recommendations to the Administrator with respect to the disposition of the application based upon its scientific and technical merit. The peer review panel may recommend to the Administrator that an application:

(A) Be given consideration for funding,

(B) Be deferred for a later decision, pending receipt of additional information, or

(C) Not be given further consideration.

(iii) For each application recommended for further consideration by the Administrator, the report shall also provide a priority score based on the scientific and technical merit of the proposed project, and make recommendations on the appropriate project period and level of support. The report may also address, as applicable, the degree to which the proposed project relates to AHCPR-announced priorities.

(b) *Procedural adjustments for small grants.* (1) The Administrator may make adjustments in the peer review procedures established in accordance with paragraph (a) of this section for grant applications with total direct costs that do not exceed the amount specified in section 922(d)(2) of the PHS Act, hereafter referred to as ''small grants.''

(2) Non-Federal and Federal experts will be selected by the Administrator for the review of small grant applications on the basis of their training and experience in particular scientific and technical fields, their knowledge of health services research and the application of research findings, and their special knowledge of the issue(s) being addressed or methods and technology being used in the specific proposal.

(3) Review of applications for small grants may be by a review group established in accordance with paragraph (a) of this section, or by individual field readers, or by an ad hoc group of reviewers.

(4) The review criteria set forth in paragraph (c) of this section shall be used for the review of small grant applications.

(5) Each reviewer or group of reviewers to whom an application has been submitted under paragraph (b) of this section shall make a written report to the Administrator on each application. Each report shall summarize the findings of the review and provide a recommendation to the Administrator on whether the application should be given further consideration. For applications recommended for further consideration, the report may also address, as applicable, the degree to which the proposed project relates to AHCPR-announced priorities.

(c) *Review criteria.* The review criteria set out in this paragraph apply to both applications reviewed by peer review panels in accordance with paragraph (a) of this section, and applications for small grants reviewed in accordance with paragraph (b) of this section.

(1) *General review criteria.* In carrying out a review under this section for grants (other than conference grants), the following review criteria will be taken into account, where appropriate:

(i) The significance and originality from a scientific or technical standpoint of the goals of the project;

(ii) The adequacy of the methodology proposed to carry out the project;

(iii) The availability of data or the adequacy of the proposed plan to collect data required in the analyses;

(iv) The adequacy and appropriateness of the plan for organizing and carrying out the project;

(v) The qualifications and experience of the principal investigator and proposed staff;

(vi) The reasonableness of the budget and the time frame for the project, in relation to the work proposed;

(vii) The adequacy of the facilities and resources available to the grantee;

(viii) The extent to which women and minorities are adequately represented in study populations;

(ix) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects; and

(x) Any additional criteria that may be announced by the Administrator from time to time for specific categories of grant applications (e.g., proposed projects for support of research centers) eligible for support under this subpart.

(xi) In addition to the scientific and technical criteria above, peer reviewers may be asked to consider the degree to which a proposed project addresses any special AHCPR priorities that have been announced by the Administrator, as applicable.

(2) *Review criteria for conference grants.* In carrying out reviews of conference grants under paragraphs (a) and (b) of this section, the following review criteria will be taken into account, as appropriate:

(i) The significance of the proposed conference, specifically the importance of the issue or problem being addressed, including methodological or technical issues for dealing with the development, conduct, or use of health services research;

(ii) The qualifications of the staff involved in planning and managing the conference;

(iii) The adequacy of the facilities and other resources available for the conference;

(iv) the appropriateness of the proposed budget, including other sources of funding;

(v) The extent to which the health concerns of women and minorities will be addressed in the conference topic(s), as appropriate;

(vi) The plan for evaluating and disseminating the results of the conference; and

(vii) Any additional criteria that may be announced by the Administrator.

(viii) In addition to the scientific and technical criteria above, peer reviewers may be asked to consider the degree to which a proposed project addresses any special AHCPR priorities that have been announced by the Administrator, as appropriate.

(d) *Conflict of interest.* (1) Members of peer review groups will be screened for potential conflicts of interest prior to appointment and will be required to follow Department policies and procedures consistent with the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), Executive Order 12674 (as modified by Executive Order 12731).

(2) In addition to any restrictions referenced under paragraph (d)(1) of this section:

(i) No member of a peer review group (or individual reviewer) may participate in or be present during any review by such group of a grant application in which, to the member's knowledge, any of the following has a financial interest:

(A) The member or his or her spouse, minor child, or partner;

(B) Any organization in which the member is serving as an officer, director, trustee, general partner, or employee; or

(C) Any organization with which the member is negotiating or has any arrangement concerning prospective employment or other similar association, and further;

(ii) In the event that any member of a peer 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 grant application, that member of the group, or the group, may be disqualified from the review and the review conducted by another group with the expertise to do so. An ad hoc group selected in accordance with §67.15(a), or §67.15(b) as applicable, may also be used for the review. Any individual reviewer to whom the conditions of this paragraph apply would also be disqualified as a reviewer.

(iii) No member of a peer review group or individual may participate in any review under this subpart of a specific grant application for which the member has had or is expected to have any other responsibility or involvement (whether preaward or postaward) as an officer or employee of the United States.

(3) Where permissible under the standards and order(s) cited in paragraph (d)(1) of this section, the Administrator may waive the requirements in paragraph (d)(2) of this section if it is determined that there is no other practical means for securing appropriate expert advice on a particular grant application.

[62 FR 12909, Mar. 18, 1997, as amended at 62 FR 37124, July 10, 1997]

§67.16 Evaluation and disposition of application.

(a) *Evaluation.* After appropriate peer review in accordance with §67.15, the Administrator will evaluate applications recommended for further consideration, taking into account, among other factors:

(1) The degree to which the purposes of Title IX of the PHS Act and section 1142 of the Social Security Act, as applicable, are being addressed;

(2) Recommendations made by reviewers pursuant to §67.15;

(3) Any recommendations made by the National Advisory Council for Health Care Policy, Research, and Evaluation, as applicable;

(4) The appropriateness of the budget;

(5) The extent to which the research proposal and the fiscal plan provide assurance that effective use will be made of grant funds;

(6) The demonstrated business management capability of the applicant;

(7) The demonstrated competence and skill of the staff, especially the senior personnel, in light of the scope of the project;

(8) The probable usefulness of the results of the project for dealing with national health care issues, policies, and programs; and