

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Public Health Service****42 CFR Part 67**

RIN 0919-AAOO

Health Services Research, Evaluation, Demonstration, and Dissemination Projects; Peer Review of Grants and Contracts

AGENCY: Agency for Health Care Policy and Research, HHS.

ACTION: Final regulations.

SUMMARY: This final rule establishes regulations for grants for health services research, evaluation, demonstration, and dissemination projects administered by the Agency for Health Care Policy and Research (AHCPR). It revises existing regulations governing health services research grants as administered by the former National Center for Health Services Research (NCHSR). The regulations set out program and administrative requirements for grantees and potential grant applicants, and describe the technical and scientific peer review by which applications for grants are to be evaluated. The regulations also establish procedures for the conduct of peer review of AHCPR contracts for health services research, evaluation, demonstration, and dissemination projects.

EFFECTIVE DATE: The final regulations are effective March 18, 1997.

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SUPPLEMENTARY INFORMATION: The final regulations revise the existing regulations at 42 CFR part 67, subpart A, and substitute a new subpart B, to reflect the establishment of the Agency for Health Care Policy and Research (AHCPR) and its legislative mandates as set forth in Pub. L. 101-239, the Omnibus Budget Reconciliation Act of 1989 (OBRA of 1989), enacted on December 19, 1989. Section 6103 of Pub. L. 101-239 added a new Title IX to the Public Health Service (PHS) Act (42 U.S.C. 299-299c-6), which established AHCPR and provided that the Secretary of Health and Human Services (HHS) shall act through the Administrator of AHCPR in carrying out the authorities under Title IX. Pub. L. 102-410, the Agency for Health Care

Policy and Research Reauthorization Act (October 13, 1992), further amended Title IX, and these amendments are reflected in the final regulations, as well. Technical amendments to Title IX subsequently included in section 2013 of Pub. L. 103-43, the National Institutes of Health Revitalization Act of 1993, did not affect this rule.

A Notice of Proposed Rulemaking (NPRM) was published in the Federal Register on November 16, 1993 (58 FR 60510), with a 60-day comment period. No public comments were received.

Background

The AHCPR is charged with enhancing the quality, appropriateness, and effectiveness of health care services, and access to such services. The AHCPR achieves these goals through the establishment of a broad base of scientific research, and through the promotion of improvements in clinical practice (including the prevention of diseases and other health conditions) and in the organization, financing, and delivery of health services. In carrying out these functions, AHCPR has built on and expanded the work supported over twenty years by its predecessor, the National Center for Health Services Research and Health Care Technology Assessment (NCHSR).

Title IX, in particular sections 902 and 925(c), authorizes the Administrator to award grants to, and enter into cooperative agreements with, public and private nonprofit entities and individuals to support research, demonstration projects, evaluations, and dissemination of information, on health care services and systems for the delivery of these services. When appropriate, the Administrator also may enter into contracts with individuals, as well as public and private entities.

Section 902(d) of the PHS Act, as amended by Pub. L. 102-410, specifies that the Administrator may provide financial assistance for the costs of developing and operating centers for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis for carrying out the purposes of Title IX.

Under section 902(e), as amended by Pub. L. 102-410, AHCPR may use its Title IX authorities to carry out, and coordinate appropriately with, activities authorized by the Social Security Act, including experiments, demonstration projects, and other related activities. Further, section 902(e) requires that research and other activities conducted under Title IX on the outcomes of health care services and procedures which affect the Medicare and Medicaid

programs be consistent with the provisions of section 1142 of the Social Security Act, which, like Title IX, was enacted by section 6103 of Pub. L. 101-239 (OBRA of 1989). The authorities in section 1142 (42 U.S.C. 1320-12b) enhance and elaborate on AHCPR's mandate to conduct and support outcomes and effectiveness research under Title IX.

Section 1142(a)(1) directs the Secretary, acting through the Administrator of AHCPR, to support research with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures, in order to identify the manner in which diseases, disorders, and other health conditions can be prevented, diagnosed, treated, and managed most effectively. Section 1142(a)(2) authorizes evaluations of the comparative effects on health and functional capacity and of alternative services and procedures for preventing, diagnosing, treating, and managing health conditions.

Also provided for in section 1142(c), for the purpose of facilitating outcomes and effectiveness research, are various authorities to conduct and support activities such as the improvement of methodologies, criteria, and data bases used in outcomes and effectiveness research; and research and demonstrations on the use of claims data and data on the clinical and functional status of patients.

Section 1142(e) requires the Secretary (through AHCPR) to provide for dissemination of the findings of outcomes and effectiveness research conducted or supported under section 1142 and clinical practice guidelines under sections 911-914 of the PHS Act. Section 1142(e)(2) provides that the Secretary (through AHCPR) will work with professional associations, medical organizations, and other relevant groups to identify and implement effective means to educate health care providers, practitioners, educators, consumers, and policymakers in using research findings and guidelines. Authority to support evaluations of the impact of such dissemination activities, and authority to support research with respect to improving methods of disseminating information on the effectiveness and appropriateness of health care services and procedures, are provided under sections 1142 (f) and (g).

Pub. L. 102-410 amended section 924(a) of the PHS Act to require that the Administrator define by regulation what constitutes financial interests that could reasonably be expected to create a bias in the results of AHCPR-supported grants, cooperative agreements, or contract projects; and the actions that

will be taken in response to any such interests. Pub. L. 103-43 included similar requirements for the National Institutes of Health (NIH) regarding protection against financial conflicts of interest in certain projects of research. A final regulation on Objectivity in Research was published by the Department in the Federal Register on July 11, 1995 (60 FR 35810). This final rule implements both AHCPR and NIH statutory requirements for regulations on conflicts of interest in research projects, and also applies broadly to all research funded by the Public Health service agencies of the Department, except Phase I projects under the Small Business Innovation Research (SBIR) program.

The Final Regulations

The provisions in AHCPR final regulations are essentially the same as those in the NPRM. Modifications incorporated for improved clarity and increased flexibility are discussed below. Other technical and editorial changes have also been incorporated.

Subpart A

The regulations at subpart A establish program and administrative requirements governing grants and cooperative agreements to carry out the purposes of Title IX of the PHS Act and section 1142 of the Social Security Act. The regulations set out the technical and scientific peer review procedures and criteria by which applications for grants and cooperative agreements are to be reviewed, in accordance with section 922(e) of the PHS Act (42 U.S.C. 229c-1(e)).

Section 67.13 Eligible Projects

The listing of eligible projects dealing with "health care technology" (paragraph (d)) has been reworded from the NPRM to read: "Health care technologies, facilities, and equipment, including assessments of health care technologies and innovative approaches to such assessments, and technology diffusion." This new language reflects the emphasis of Pub. L. 102-410 on innovation in approaches to technology assessments. The category dealing with special populations now explicitly lists women and children, and dissemination has been expanded to include examples of the range of audiences to whom AHCPR efforts are directed.

Section 67.15 Peer Review of Applications

Proposed § 67.15(a), by exempting "small grants" from review by established peer review groups and procedures, would have inadvertently

restricted the flexibility for review of small grants provided by section 922(d)(2) of the PHS Act. Section 922(d)(2) permits the Administrator to make adjustments in the standard review procedures for "small grant" applications, which have direct costs that will not exceed the amount specified in 922(d)(2) (currently \$50,000). These adjustments may be made for the purpose of encouraging the entry of individuals into the field of research and promoting clinical practice-oriented research, as well as for other purposes which the Administrator may determine.

Accordingly, paragraphs (a) and (b) have been modified and retitled to allow for "small grants" to be reviewed by established peer review groups, as well as to permit adjustments in the procedures, such as review by field readers and ad hoc groups. Paragraph (b) describes the procedures for adjusting the peer review process for "small grants." The new titles are, respectively, "General procedures for peer review" and "Procedural adjustments for small grants." These modifications will ensure maximum flexibility for the Administrator, which is consistent with section 922(d)(2).

Section 67.15(c)(1) General Review Criteria

The NPRM included as a proposed review criterion, "The degree to which the proposed project addresses the purposes of Title IX of the PHS Act and section 1142 of the Social Security Act * * *" This has been moved to § 67.16, "Evaluation and disposition of applications." Assuring that broad legislative mandates are being met is part of AHCPR's overall program and funding decision processes, rather than the scientific and technical review of individual applications. The second half of the proposed criterion, the degree to which the proposed project addresses "any special AHCPR priorities that have been announced by the Administrator," has been retained for reviewers' consideration, as applicable.

Also, the review criteria under § 67.15(c)(1) have been expanded to include, "The extent to which women and minorities are adequately represented in study populations." This is consistent with AHCPR's commitment and current requirements, as provided in application materials, to ensure wide and appropriate representation in study populations.

Section 67.15(c)(2) Review Criteria for Conference Grants

This section has been streamlined so that the final regulation includes only

the broad general review criteria for conference grants, comparable to the criteria for non-conference grants. Additional detailed criteria may be included in published program announcements, which permit more flexibility for AHCPR in assuring that the criteria are responsive to the changing needs of the health care community.

Also, included in the final review criteria is: "The extent to which the health concerns of women and minorities will be addressed in conference topic(s), as appropriate." This addition makes the conference grants criteria parallel to the criteria under § 67.15(c)(1) and reflects AHCPR's commitment to encourage wide and appropriate representation of the health concerns of women and minorities in all of its activities.

Consistent with § 67.15(c)(1), "The degree to which the proposed project addresses the purposes of Title IX of the PHS Act and section 1142 of the Social Security Act * * *" has been moved to § 67.16. The degree to which a proposed project addresses "any special AHCPR priorities that have been announced by the Administrator" has been retained for reviewers' consideration, as applicable.

Section 67.16 Evaluation and Disposition of Applications

"The degree to which the proposed project addresses the purposes of Title IX of the PHS Act and section 1142 of the Social Security Act" included in the NPRM as a peer review criterion is contained in the final regulations under paragraph § 67.16(a). As discussed above, the degree to which the overall legislative purposes are being addressed is a part of the AHCPR program and policy funding decision process, as the Administrator seeks to ensure a broad and balanced portfolio of health services research. (See discussions of § 67.15(c)(1) and § 67.15(c)(2).)

Section 67.17 Grant Award

Proposed § 67.17(g) regarding supplemental awards has been reworded to improve clarity.

Proposed § 67.17(h) would have continued to require peer review of all noncompeting continuation applications for projects with a project period in excess of 2 years and with direct costs in excess of the amount specified in section 922(d)(2) of the PHS Act (small grants currently at \$50,000). This was consistent with longstanding AHCPR requirements and practices. AHCPR believes that, in keeping with the Administration's Reinventing Government Initiative, it is important to allow more flexibility in these review

procedures and to use peer reviewers in the most efficient way. The final regulations ensure this flexibility by providing that AHCPR may require peer review of noncompeting continuation applications, but do not mandate such reviews.

Subpart B

The existing regulations at subpart B pertain to grants for health services research centers under former section 305(e) of the PHS Act (originally section 305(d)), which described specific types of research centers to be supported, and mandated particular requirements for each center. Pub. L. 101-239 repealed section 305 of the PHS Act in its entirety and provided broad authority for support to multidisciplinary health services research centers under Title IX of the PHS Act. See section 902(d), as amended by Pub. L. 102-410 (42 U.S.C. 299a(d)). Pub. L. 101-239 also provided broad authority for support of research centers for the conduct of outcomes research under section 1142(c) of the Social Security Act (42 U.S.C. 1320b-12(c)(4)). Grants for centers under Title IX of the PHS Act and section 1142(c) of the Social Security Act are made in accordance with subpart A. Therefore, the Department is removing the existing subpart B, which is obsolete, and adding a new subpart B pertaining to the peer review of contract proposals as required by section 922(e) of the PHS Act (42 U.S.C. 299c-1(e)). All other aspects of AHCPR contract administration and management are conducted in accordance with the Federal Acquisition Regulations (FAR) and the Health and Human Services Acquisition Regulations (HHSAR).

Section 922 of the PHS Act requires that technical and scientific peer review shall be conducted not only with respect to each application for a grant or cooperative agreement, but also with respect to each proposal for a contract under Title IX. Section 922(e) further requires that regulations be issued for the conduct of such peer review. The new Subpart B satisfies this requirement with respect to the peer review of contracts. The regulations in this subpart are to be used in conjunction with the FAR and the HHSAR, which govern all Department contracts.

The regulations apply to the peer review of contract proposals under section 1142 of the Social Security Act (42 U.S.C. 1320b-12), as well as Title IX of the PHS Act. This is consistent with the interrelationship between the two authorities. The peer review requirements in § 67.102 are applicable to all contract proposals, regardless of the projected costs of the contracts.

(Section 922(d)(2) of the PHS Act does not provide for procedural adjustments in the peer review process for contract proposals as it does for applications for small grants as set out in § 67.15(b) of subpart A.)

Smoke-Free Workplace

The Department and its Public Health Service agencies strongly encourage all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Pub. L. 103-227, The Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the Public Health Service mission to protect and advance the physical and mental health of the American people.

Executive Order 12866 and Regulatory Flexibility Act

The final regulations have been reviewed in accordance with the requirements of Executive Order No. 12866, "Regulatory Planning and Review." The Secretary, therefore, has determined that the regulations do not constitute a major rule, as defined under the order and, as a result, have not been reviewed by the Office of Management and Budget. In addition, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), it is certified that the regulations will not have a significant economic impact on a substantial number of small entities. The regulations make minor revisions to the existing grant and contract procedures, and do not impose any consequential costs on the grantees or contractors. Therefore, the Secretary has determined that a regulatory impact analysis is not required.

Paperwork Reduction Act of 1995

The final regulations do not contain any new reporting or recordkeeping requirements subject to review and clearance under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The applications used for the programs covered by the regulations at 42 CFR part 67, subpart A, (PHS Form 398 "Application for Public Health Service Grant and HS Form 2590 "Application for Continuation of Public Health Service Grant," and PHS Form 5161 "Application for State and Local Governments"), are approved under OMB Approval Nos. 0925-0001 and 0937-0189.

List of Subjects in 42 CFR Part 67

Grant programs—Health services research, evaluation, demonstration, and dissemination projects; peer review of grants and contracts.

Dated: February 14, 1997.

Clifton R. Gaus,

Administrator, Agency for Health Care Policy and Research.

(Catalog of Federal Domestic Assistance No. 93n226—Health Services Research and Development Grants, and No. 93.180—Medical Effectiveness Research)

Accordingly, 42 CFR part 67 is revised to read as follows:

Part 67—Agency for Health Care Policy and Research Grants and Contracts

Subpart A—Research Grants for Health Services Research, Evaluation, Demonstration, and Dissemination Projects

Sec.

- 67.10 Purpose and scope.
- 67.11 Definitions.
- 67.12 Eligible applicants.
- 67.13 Eligible projects.
- 67.14 Application.
- 67.15 Peer review of applications.
- 67.16 Evaluation and disposition of applications.
- 67.17 Grant award.
- 67.18 Use of project funds.
- 67.19 Other applicable regulations.
- 67.20 Confidentiality.
- 67.21 Control of data and availability of publications.
- 67.22 Additional conditions.

Subpart B—Peer Review of Contracts for Health Services Research, Evaluation, Demonstration, and Dissemination Projects

- 67.101 Purpose and scope.
- 67.102 Definitions.
- 67.103 Peer review of contract proposals.
- 67.104 Confidentiality.
- 67.105 Control of data and availability of publications.

Authority: Pub. L. 103-43, 107 Stat. 214-215, Pub. L. 102-410, 106 Stat. 2094-2101 and sec. 6103, Pub. L. 101-239, 103 Stat. 2189-2208, Title IX of the Public Health Service Act (42 U.S.C. 299-299c-6); and sec. 1142, Social Security Act (42 U.S.C. 1320b-12).

Subpart A—Research Grants for Health Services Research, Evaluation, Demonstration, and Dissemination Projects

§ 67.10 Purpose and scope.

The regulations of this subpart apply to the award by AHCPR of grants and cooperative agreements under:

(a) Title IX of the Public Health Service Act to support research, evaluation, demonstration, and dissemination projects, including conferences, on health care services and systems for the delivery of such services, as well as to establish and

operate multidisciplinary health services research centers.

(b) Section 1142 of the Social Security Act to support research on the outcomes, effectiveness, and appropriateness of health care services and procedures, including but not limited to, evaluations of alternative services and procedures; projects to improve methods and data bases for outcomes, effectiveness, and other research; dissemination of research information and clinical guidelines, conferences, and research on dissemination methods.

§ 67.11 Definitions.

As used in this subpart—

Administrator means the Administrator and any other officer or employee of the Agency for Health Care Policy and Research to whom the authority involved may be delegated.

Agency for Health Care Policy and Research (AHCPR) means that unit of the Department of Health and Human Services established by section 901 of the Public Health Service Act.

Direct costs means the costs that can be identified specifically with a particular cost objective, such as compensation of employees for the time and effort devoted specifically to the approved project, and the costs of materials acquired, consumed, or expended specifically for the purpose of the approved project.

Grant means an award of financial assistance as defined in 45 CFR parts 74 and 92, including cooperative agreements.

Grantee means the organizational entity or individual to which a grant, including a cooperative agreement, under Title IX of the Public Health Service Act or section 1142 of the Social Security Act and this subpart is awarded and which is responsible and accountable both for the use of the funds provided and for the performance of the grant-supported project or activities. The grantee is the entire legal entity even if only a particular component is designated in the award document.

Nonprofit as applied to a private entity, means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any shareholder or individual.

Peer review group means a panel of experts, established under section 922(c) of the PHS Act, who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group as set out in this subpart. Officers and employees of the United States may not constitute more than 25 percent of the

membership of any such group under this subpart.

PHS Act means the Public Health Service Act, as amended.

Principal investigator means a single individual, designated in the grant application and approved by the Administrator, who is responsible for the scientific and technical direction of the project.

Social Security Act means the Social Security Act, as amended.

§ 67.12 Eligible applicants.

Any public or nonprofit private entity or any individual is eligible to apply for a grant under this subpart.

§ 67.13 Eligible projects.

Projects for research, evaluations, demonstrations, dissemination of information (including research on dissemination), and conferences, related to health care services and the delivery of such services, are eligible for grant support. These include, but are not limited to, projects in the following categories:

- (a) Effectiveness, efficiency, and quality of health care services;
- (b) Outcomes of health care services and procedures;
- (c) Clinical practice, including primary care and practice-oriented research;
- (d) Health care technologies, facilities, and equipment, including assessments of health care technologies and innovative approaches to such assessments, and technology diffusion;
- (e) Health care costs and financing, productivity, and market forces;
- (f) Health promotion and disease prevention;
- (g) Health statistics and epidemiology;
- (h) Medical liability;
- (i) AID/HIV infection, particularly with respect to issues of access and delivery of health care services;
- (j) Rural health services;
- (k) The health of low-income, minority, elderly, and other underserved populations, including women and children; and
- (l) Information dissemination and research on dissemination methodologies, directed to health care providers, practitioners, consumers, educators, review organizations, and others.

§ 67.14 Application

(a) To apply for a grant, an entity or individual must submit an application in the form and at the time that the 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 number 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.

§ 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

(9) The degree to which AHCPR-announced priorities or purposes are being addressed.

(b) *Disposition.* On the basis of the evaluation of the application as

provided in paragraph (a) of this section, the Administrator shall: give consideration for funding, defer for a later decision, pending receipt of additional information, or give no further consideration for funding, to any application for a grant under this subpart; except that the Administrator may not fund an application which has not been recommended for further consideration as a result of peer review in accordance with § 67.15. A recommendation against further consideration shall not preclude reconsideration, if the application is revised, responding to issues and questions raised during the review, and resubmitted for peer review at a later date.

§ 67.17 Grant award.

(a) Within the limits of available funds, the Administrator may award grants to those applicants whose projects are being considered for funding, which in the judgment of the Administrator, will promote best the purposes of Title IX of the PHS Act and (if applicable) section 1142 of the Social Security Act, AHCPR priorities, and the regulations of this subpart.

(b) The Notice of Grant Award specifies how long the Administrator intends to support the project without requiring the project to re compete for funds. This period, called the project period, will usually be for 3–5 years, except for small grants, which usually are 1 year awards. The project period as specified in the Notice of Grant Award shall begin no later than 9 months following the date of the award, except that the project period must begin in the same fiscal year as that from which funds are being awarded.

(c) Upon request from the grantee, Department grants policy permits an extension of the project period for up to 12 months, without additional funds, when more time is needed to complete the research. The Administrator may approve a request for an additional extension of time based on unusual circumstances with written justification submitted by the grantee, prior to the completion of the project period. In no case will an additional extension of more than 12 months be approved.

(d) Generally, a grant award will be for 1 year, and subsequent continuation awards will be for 1 year at a time. A grantee must submit a separate continuation application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices and the

availability of funds. In all cases, continuation awards require a determination by the Administrator that continuation is in the best interest of the Federal Government.

(e) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application.

(f) *Small grants.* For particular categories of small grants, such as dissertation research support, the Administrator may establish a limit on total direct costs to be awarded. Any categorical limits will be announced in advance of the deadline for receipt of applications for such small grants.

(g) *Supplemental awards.* (1) Except for small grants, supplemental awards that would exceed 20 percent of the AHCPR approved direct costs of the project during the project period, or that request an increase in funds to support a change or a significant expansion of the scope of the project, will be reviewed as competing supplemental grants in accordance with § 67.15(a). A supplemental award for preparation of data in suitable form for transmittal in accordance with § 67.21 shall be excluded from the 20 percent aggregate.

(2) In the case of small grants, as defined in section 922(d)(2) of the PHS Act, the Administrator will not approve a supplemental award during the project period (excluding any supplemental award for preparation of data in suitable form for transmittal in accordance with § 67.21) that will, in the aggregate, exceed 10 percent of the AHCPR approved direct costs of the project.

(h) *Noncompeting continuation awards.* Each project with a project period in excess of 2 years and with direct costs over the project period in excess of the amount specified in section 922(d)(2) may be reviewed during the second budget period and during each subsequent budget period by at least two members of the peer review group that reviewed the initial application, or individuals who participated in that review, to the extent practicable. Recommendations to the Administrator for continuation support will be based upon evaluation of:

(1) The progress of the project in meeting project objectives;

(2) The appropriateness of the management of the project and allocation of resources within the project;

(3) The adequacy and appropriateness of the plan for carrying out the project during the budget period in light of the

accomplishments during previous budget periods; and

(4) The reasonableness of the proposed budget for the subsequent budget period.

§ 67.18 Use of project funds.

Grant funds must be spent solely for carrying out the approved project in accordance with Title IX of PHS Act, section 1142 of the Social Security Act (if applicable), the regulations of this subpart, the terms and conditions of the award, and the provisions of 45 CFR part 74, or part 92 for State and local government grantees.

§ 67.19 Other applicable regulations.

Several other regulations apply to grants under this subpart. These include, but are not limited to:

- 37 CFR Part 401—Inventions and patents
- 42 CFR Part 50 Subpart A—Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science
- 42 CFR Part 50 Subpart D—Public Health Service grant appeals procedure
- 42 CFR Part 50 Subpart F—Responsibility of applicants for promoting objectivity in research for which PHS funding is sought
- 45 Part 16—Procedures of the departmental grant appeals board
- 45 CFR Part 46—Protection of human subjects
- 45 CFR Part 74—Administration of grants
- 45 CFR Part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)
- 45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964
- 45 CFR Part 81—Practice and procedure for hearings under Part 80 of this title
- 45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR Part 91—Nondiscrimination on the basis of age in DHHS programs or activities receiving Federal financial assistance
- 45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements with State and local governments
- 45 CFR Part 93—New restrictions on lobbying

§ 67.20 Confidentiality.

The confidentiality of identifying information obtained in the course of conducting or supporting grant and cooperative agreement activities under

this subpart is protected by section 903(c) of the PHS Act. Specifically:

(a) No information obtained in the course of conducting or supporting grant and cooperative agreement activities under this subpart, if the entity or individual supplying the information or described in it is identifiable, may be used for any purpose other than the purpose for which it was supplied, unless the identifiable entity or individual supplying the information or described in it has consented to such other use, in the recorded form and manner as the Administrator may require; and

(b) No information obtained in the course of grant and cooperative agreement activities conducted or supported under this subpart may be published or released in other form if the individual who supplied the information or who is described in it is identifiable, unless such individual has consented, in the recorded form and manner as the Administrator may require, to such publication or release.

§ 67.21 Control of data and availability of publications.

Except as otherwise provided in the terms and conditions of the award and subject to the confidentiality requirements of section 903(c) of the PHS Act, section 1142(d) of the Social Security Act, and § 67.20 of this subpart:

(a) All data collected or assembled for the purpose of carrying out health services research, evaluation, demonstration, or dissemination projects supported under this subpart shall be made available to the Administrator, upon request:

(b) All publications, reports, papers, statistics, or other materials developed from work supported, in whole or in part, by an award made under this subpart must be submitted to the Administrator in a timely manner. All such publications must include an acknowledgement that such materials are the results of, or describe, a grant activity supported by AHCPR;

(c) The AHCPR retains a royalty-free, non-exclusive, and irrevocable license to reproduce, publish, use, or disseminate any copyrightable material developed in the course of or under a grant for any purpose consistent with AHCPR's statutory responsibilities, and to authorize others to do so for the accomplishment of AHCPR purposes; and

(d) Except for identifying information protected by section 903(c) of the PHS Act, the Administrator, as appropriate, will make information obtained with AHCPR grant support available, and arrange for dissemination of such

information and material on as broad a basis as practicable and in such form as to make them as useful as possible to a variety of audiences, including health care providers, practitioners, consumers, educators, and policymakers.

§ 67.22 Additional conditions.

The Administrator may, with respect to any grant awarded under this subpart, impose additional conditions prior to or at the time of any award when in the Administrator's judgment such conditions are necessary to assure or protect advancement of the approved project, the interest of the public health, or the conservation of grant funds.

Subpart B—Peer Review of Contracts for Health Services Research, Evaluation, Demonstration, and Dissemination Projects

§ 67.101 Purpose and scope.

(a) The regulations of this subpart apply to the peer review of contracts under:

(1) Title IX of the Public Health Service Act to support research, evaluation, demonstration, and dissemination projects, including conferences, on health care services and systems for the delivery of such services; and development of clinical practice guidelines, quality standards, performance measures, and review criteria.

(2) Section 1142 of the Social Security Act to support research on the outcomes, effectiveness, and appropriateness of health care services and procedures, including, but not limited to, evaluations of alternative services and procedures; projects to improve methods and data bases for outcomes and effectiveness research; dissemination of research information and clinical practice guidelines, as well as quality standards, performance measures, and review criteria; conferences; and research on dissemination methods.

(b) The regulations of this subpart also contain provisions respecting confidentiality of research data, control of data, and availability of information.

§ 67.102 Definitions.

Contract proposal means a written offer to enter into a contract submitted to a contracting officer by an individual or non-Federal organization, and including at a minimum a description of the nature, purpose, duration, cost of project and methods, personnel, and facilities to be utilized in carrying out the requirements of the contract.

Peer review group means a panel of experts, as required by section 922(c) of

the PHS Act, established to conduct technical and scientific review of contract proposals and to make recommendations to the Administrator regarding the merits of such proposals.

Request for proposals means a Government solicitation to prospective offerors, under procedures for negotiated contracts, to submit a proposal to fulfill specific agency requirements based on terms and conditions defined in the solicitation. The solicitation contains information sufficient to enable all offerors to prepare competitive proposals, and is as complete as possible with respect to: The nature of work to be performed; descriptions and specifications of items to be delivered; performance schedule; special requirements, clauses or other circumstances affecting the contract; and criteria by which the proposals will be evaluated.

§ 67.103 Peer review of contract proposals.

(a) All contract proposals for AHCPH support will be submitted by the Administrator for review to a peer review group, as required in section 922(a) of the PHS Act. Proposals will be reviewed in accordance with the Federal Acquisition Regulations and the Health and Human Services Acquisition Regulations (48 CFR Ch. I and III) and the requirements of the pertinent Request for Proposal.

(b) *Establishment of peer review groups.* In accordance with section 922(c) of the PHS Act, the Administrator shall establish such peer review groups as may be necessary to review all contract proposals submitted to AHCPH.

(c) *Composition of peer review groups.* The peer review groups shall be composed of individuals, in accordance with section 922(c) of the PHS Act, as amended, who by virtue of their training or experience are eminently qualified to carry out the duties of such a peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Members of the peer review group will be selected based upon their training or experience in relevant scientific and technical fields, taking into account, among other factors:

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

(2) 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;

(3) 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;

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

(5) Appropriate representation based on gender, racial/ethnic origin, and geography, to the extent practicable.

(d) *Term of peer review group members.* Notwithstanding section 922(c)(3) of the PHS Act, members of peer review groups appointed to review contract proposals will be appointed to such groups for a limited period of time, as determined by the Administrator; such as on an annual basis, or until the peer review of the contract proposals is completed, or until the expiration of the contract(s) awarded as a result of the peer review.

(e) *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) and Executive Order 12674 (as modified by Executive Order 12731).

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

(i) No member of a peer review group may participate in or be present during any review by such group of a contract proposal 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 any member of a peer review group or his or her spouse, parent, child, or partner is currently or expected to be the project director or member of the staff responsible for carrying out any contract requirements as specified in the contract proposal, that member is disqualified and will be replaced as appropriate.

§ 67.104 Confidentiality.

Identifying information obtained in the course of conducting AHCPH contract activities under this subpart is protected by section 903(c) of the PHS Act. Specifically:

(a) No information obtained in the course of conducting AHCPH contract activities under this subpart, if the entity or individual supplying the information or described in it is identifiable, may be used for any purpose other than the purpose for which it was supplied, unless the identifiable entity or individual supplying the information or described in it has consented to such other use, in the recorded form and manner as the Administrator may require.

(b) No information obtained in the course of conducting AHCPH contract activities under this subpart may be published or released in other form if the individual who supplied the information or who is described in it is identifiable, unless such individual has consented, in the recorded form and manner as the Administrator may require, to such publication or release.

§ 67.105 Control of data and availability of publications.

(a) Data will be collected, maintained, and supplied as provided in each contract subject to the confidentiality requirements of section 903(c) of the PHS Act, section 1142(d) of the Social Security Act, and § 67.104 of this subpart.

(b) All publications, reports, papers, statistics, or other materials developed from work supported in whole or in part by contracts under Title IX of the PHS Act or section 1142 of the Social Security Act, if applicable, must be submitted to the Administrator in accordance with the terms of the contract. All publications must include an acknowledgment that such materials are the results of, or describe, a contractual activity supported by AHCPH.

(c) In accordance with 48 CFR 52.227-14, unless otherwise specified in the contract, AHCPH will retain a license to use, disclose, reproduce, prepare derivative works from, distribute copies to the public, and perform publicly and display publicly any copyrightable materials produced under a contract for any purpose consistent with AHCPH's statutory responsibilities, and to have or permit others to do so for accomplishment of AHCPH purposes.

(d) Except for identifying information protected by section 903(c) of the PHS Act, the Administrator, as appropriate, will make information provided in

accordance with paragraphs (a) and (b) of this section available, and arrange for dissemination of such information and materials on as broad a basis as practicable and in such form as to make them as useful as possible to a variety of audiences, including health care providers, practitioners, consumers, educators, and policymakers.

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