

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, in-

cluding 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;

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- (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 ad-

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justed 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