

**§ 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 AHCPR 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 AHCPR.

(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