

## § 52h.9

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

(e) The scientific environment and reasonable availability of resources necessary to the research;

(f) The adequacy of plans to include both genders, minorities, children and special populations as appropriate for the scientific goals of the research;

(g) The reasonableness of the proposed budget and duration in relation to the proposed research; and

(h) The adequacy of the proposed protection for humans, animals, and the environment, to the extent they may be adversely affected by the project proposed in the application.

### **§ 52h.9 What matters must be reviewed for unsolicited contract proposals?**

(a) Except as otherwise provided by law, no awarding official shall award a contract based upon an unsolicited contract proposal covered by this part unless the proposal has been reviewed by a peer review group in accordance with the provisions of this part and the group has made recommendations concerning the scientific merit of that proposal.

(b) Except to the extent otherwise provided by law, peer review group recommendations are advisory only and not binding on the awarding official.

### **§ 52h.10 What matters must be reviewed for solicited contract proposals?**

(a) Subject to paragraphs (b) and (c) of this section, no awarding official shall issue a request for contract proposals with respect to a contract project involving solicited contract proposals, unless the project concept has been reviewed by a peer review group or advisory council in accordance with this part and the group has made recommendations concerning the scientific merit of the concept.

(b) The awarding official may delay carrying out the requirements for peer review of paragraph (a) of this section until after issuing a request for proposals if the official determines that the accomplishment of essential program objectives would otherwise be placed in jeopardy and any further delay clearly would not be in the best

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interest of the Government. The awarding official shall specify in writing the grounds on which this determination is based. Under these circumstances, the awarding official will not award a contract until peer review of the project concept and the proposals has been completed. The request for proposals shall state that the project concept will be reviewed by a peer review group and that no award will be made until the review is conducted and recommendations made based on that review.

(c) The awarding official may determine that peer review of the project concept for behavioral or biomedical research and development contracts is not needed if one of the following circumstances applies: the solicitation is to re-compete or extend a project that is within the scope of a current project that has been peer reviewed, or there is a Congressional authorization or mandate to conduct specific contract projects. If a substantial amount of time has passed since the concept review, the awarding official shall determine whether peer review is required to ensure the continued scientific merit of the concept.

(d) Except to the extent otherwise provided by law, the recommendations referred to in this section are advisory only and not binding on the awarding official.

### **§ 52h.11 What are the review criteria for contract projects and proposals?**

(a) In carrying out its review of a project concept under § 52h.10(a) or § 52h.10(b), the peer review group shall take into account, among other pertinent factors:

(1) The significance from a scientific or technical standpoint of the goals of the proposed research or development activity;

(2) The availability of the technology and other resources necessary to achieve those goals;

(3) The extent to which there are identified, practical uses for the anticipated results of the activity; and

(4) Where the review includes the project approach, the adequacy of the methodology to be utilized in carrying out the activity.

(b) In carrying out its review of unsolicited contract proposals under § 52h.9, the peer review group shall take into account, among other pertinent factors, the criteria in § 52h.8 which are relevant to the particular proposals.

(c) In carrying out its review of solicited proposals under § 52h.10(a) or (b), the peer review group shall evaluate each proposal in accordance with the criteria set forth in the request for proposals.

**§ 52h.12 Other regulations that apply.**

The regulations in this part are in addition to, and do not supersede other regulations concerning grant applications, contract projects, or contract proposals set forth elsewhere in this title, title 45, or title 48 of the Code of Federal Regulations.

**PART 53—GRANTS, LOANS AND LOAN GUARANTEES FOR CONSTRUCTION AND MODERNIZATION OF HOSPITALS AND MEDICAL FACILITIES**

**Subparts A–K [Reserved]**

**Subpart L—Services for Persons Unable To Pay; Community Service; Nondiscrimination**

- Sec.  
53.111 Services for persons unable to pay.  
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**Subpart M [Reserved]**

**Subpart N—Loan Guarantees and Direct Loans**

- 53.154 Waiver of right of recovery.  
53.155 Modification of loans.  
53.156 Fees for modification requests.

AUTHORITY: Secs. 215, 603, 609, 621, 623, Public Health Service Act as amended, 58 Stat. 690, 78 Stat. 451 and 456, 84 Stat. 344 and 346 (42 U.S.C. 216, 291c, 291i, 291j-1 and 291j-3; 31 U.S.C. 9701).

**Subparts A–K [Reserved]**

**Subpart L—Services for Persons Unable To Pay; Community Service; Nondiscrimination.**

**§ 53.111 Services for persons unable to pay.**

(a) *Applicability.* The provisions of this section apply to every applicant which heretofore has given or hereafter will give an assurance that it will make available a reasonable volume of services to persons unable to pay therefor but shall not apply to an applicant (1) for more than 20 years after the completion of construction of any facility with respect to which funds have been paid under section 606 of the Act or (2) beyond the period during which any amount of a direct loan made under sections 610 or 623 of the Act, or any amount of a loan with respect to which a loan guarantee and interest subsidy has been provided under sections 623 and 624 of the Act remains unpaid.

(b) *Definitions.* As used in this section:

(1) The term *facility* includes hospitals, facilities for long-term care, outpatient facilities, rehabilitation facilities, and public health centers;

(2) The term *applicant* means an applicant for, or recipient of, a grant, a loan guarantee or a loan under the Act;

(3) *Fiscal year* means the fiscal year of the applicant;

(4) The term *operating costs* means the actual operating costs of the applicant for a fiscal year as determined in accordance with cost determination principles and requirements under title XVIII of the Social Security Act (42 U.S.C. 1395): *Provided*, That such “operating costs” shall be determined for the applicant’s entire facility and for all patients regardless of the source of payment for such care: *And provided further*, That in determining such operating costs there shall be deducted the amount of all actual or estimated reimbursements, as applicable, for services received or to be received pursuant to title XVIII and XIX of the Social Security Act (42 U.S.C. 1395 and 1936);

(5) The term *reasonable cost* means the cost of providing services to a specific patient determined in accordance with the cost determination principles and requirements under title XVIII of