§ 52h.6 Availability of information.

Transcripts, minutes, and other documents made available to or prepared for or by a peer review group will be available for public inspection and copying to the extent provided in the Freedom of Information Act (5 U.S.C. 552), the Federal Advisory Committee Act (5 U.S.C. App. I), the Privacy Act (5 U.S.C. 552a), and implementing Department of Health and Human Services regulations (45 CFR parts 5, 5b).

§ 52h.7 Grants; matters to be reviewed.

(a) No awarding official will make a grant based upon an application covered by this part unless the application has been reviewed by a peer review group in accordance with the provisions of this part and said group has made recommendations concerning the scientific merit of such application. In addition, where under applicable law an awarding official is required to secure the approval or advice of a national advisory council or board concerning an application, said application will not be considered by the council or board unless it has been reviewed by a peer review group in accordance with the provisions of this part and said group has made recommendations concerning the scientific merit of the application except where the council or board is the peer review group.

(b) Except to the extent otherwise provided for by law, such recommendations are advisory only and not binding on the awarding official or national advisory council or board.

§ 52h.8 Grants; review criteria.

In carrying out its review under § 52h.7, the peer review group will take into account, among other factors:

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

(b) The adequacy of the methodology proposed to carry out the research;

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

(d) The reasonable availability of resources necessary to the research;

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

(f) 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.

§ 52h.9 Unsolicited contract proposals; matters to be reviewed.

(a) No awarding official will 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 (pursuant to procedures set forth in 41 CFR subpart 3–4.52) and said group has made recommendations concerning the scientific merit of such proposal.

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

§ 52h.10 Contract projects involving solicited contract proposals; matters to be reviewed.

(a) Subject to paragraph (b) of this section, no awarding official will 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 in accordance with the provisions of this part and said group has made recommendations concerning the scientific merit of said concept. Where in the judgment of the awarding official the project approach has been sufficiently well defined by the time the review required by the preceding sentence is conducted, this review and the resulting recommendations shall include the project approach as well.

(b) The awarding official may waive the requirements of paragraph (a) of this section for peer review before issuing a request for contract proposals if he determines that the accomplishments of essential program objectives would otherwise be placed in jeopardy and any further delay would clearly not be in the best interest of the Government. The awarding official shall specify in writing the grounds on which this determination is based. Under such circumstances, the awarding official will not award a contract based on

the request for contract proposals unless the proposals received in response to the request have been reviewed by a peer review group and that group has made recommendations concerning the scientific merit of the project concept and of the approaches outlined in the proposals. The request for proposals will indicate that the project concept has not been reviewed by a peer review group and that no award will be made until such review is conducted and recommendations made based on such review.

(c) The Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse and Mental Health Administration, the Administrator of the Health Resources and Service Administration, or their designees may identify individual contracts or classes of contracts which may not be awarded unless all pertinent contract proposals have been reviewed by a peer review group in accordance with the provisions of this part and that group has made recommendations concerning the scientific merit of the proposals.

(d) Except to the extent otherwise provided for by law, such recommendations are advisory only and not binding on the awarding official.

(Sec. 215, Public Health Service Act, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, Public Health Service Act, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 2891–4); sec. 955(a), Pub. L. 97–35, 95 Stat. 590 (42 U.S.C. 300z–7(e)))

[43 FR 7862, Feb. 24, 1978, as amended at 45 FR 35328, May 27, 1980; 49 FR 38111, Sept. 27, 1984]

§ 52h.11 Contract projects and proposals; review criteria.

(a) In carrying out its review of a project concept under § 52h.10(a) or § 52h.10(b), the peer review group will take into account, among other 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 these 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 will take into account, among other factors, those criteria in § 52h.8 which are relevant to the particular proposals.

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

§ 52h.12 Applicability of other regulations.

The regulations in this part are in addition to, and do not supersede other regulations concerning grant applications, contract projects, or contract proposals appearing elsewhere in this title, title 41, or title 45 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.
53.112 Nondiscrimination.
53.113 Community service.

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]