

Public Health Service, HHS

§ 52h.2

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

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

52h.12 Applicability of other regulations.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351 (42 U.S.C. 289f-4); sec. 955(a), Pub. L. 97-35, 95 Stat. 590 (42 U.S.C. 300z-7(e)).

SOURCE: 43 FR 7862, Feb. 24, 1978, unless otherwise noted.

§ 52h.1 Applicability.

The regulations in this part apply to:

(a) Applications for grants for biomedical and behavioral research, under the Act to the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration. These regulations do not apply to applications for:

(1) Continuation funding for budget periods within an approved project period;

(2) Supplemental funding to meet increased administrative costs within a project period; or

(3) Construction grants.

(b) Biomedical and behavioral research and development contract projects administered by the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration.

(c) Applications for grants and contracts under section 2008 of the Act.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 289f-4))

[45 FR 35328, May 27, 1980, as amended at 47 FR 50261, Nov. 5, 1982; 49 FR 38111, Sept. 27, 1984]

§ 52h.2 Definitions.

As used in this part:

(a) *Act* means the Public Health Service Act, as amended.

(b) *Project period* has the same meaning as in 42 CFR part 52.

(c) *Budget period* means the interval of time (usually 12 months) into which

the project period is divided for budgetary and reporting purposes.

(d) *Awarding official* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated; *Except that*, where the Act specifically authorizes another official to make awards in connection with a particular program, the "awarding official" shall mean said other official and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(e) *Peer review group* means a group of experts qualified by training and experience in particular scientific or technical fields to give expert advice, in accordance with the provisions of this part, on the scientific and technical merit of grant applications or contract projects in those fields.

(f) *Research* means systematic study directed toward new or fuller knowledge and understanding of the subject studied.

(g) *Development* means the systematic use of knowledge and understanding gained from research, directed toward creating useful materials, devices, systems, or methods.

(h) *Research and development contract project* means an identified, circumscribed activity, involving a single contract or two or more similar, related, or interdependent contracts, intended and designed to acquire new or fuller knowledge and understanding of a subject and/or to use such knowledge and understanding to develop useful materials, devices, systems, or methods. The terms include (but are not limited to) development and utilization of resources, testing, demonstrations, clinical trials, preparation of reports, and production of experimental or test models necessary or incidental to a research and/or development activity, but exclude quantity production and routine product testing and quality control.

(i) *Project concept* means the basic purpose, scope, and objectives of the project.