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Agency: NATIONAL INSTITUTES OF HEALTH

Title: Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects

Action: Notice of proposed rulemaking.

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NATIONAL INSTITUTES OF HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 52h

RIN 0925-AA20

Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects

AGENCY: National Institutes of Health, Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Institutes of Health (NIH) is proposing to revise the regulations governing scientific peer review of research grant applications and research and development contract projects and contract proposals to clarify the review criteria, revise the conflict of interest requirements to reflect the fact that members of Scientific Review Groups do not become Federal employees by reason of that membership, and make other changes required to update the regulations.

DATES: The NIH invites written comments on the proposed regulations and requests that comments identify the regulatory provision to which they relate. Comments must be received on or before November 20, 2000.

ADDRESSES: Comments should be sent to Jerry Moore, NIH Regulations Officer, National Institutes of Health, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852. Comments also may be sent electronically by facsimile (301-402-0169) or e-mail (jm40z@nih.gov).

FOR FURTHER INFORMATION CONTACT: Jerry Moore at the address above, or telephone (301) 496-4607 (not a toll-free number).

SUPPLEMENTARY INFORMATION: Applications to NIH for grants for biomedical and behavioral research and NIH research and development contract project concepts and contract proposals are reviewed under a two-level scientific peer review system, often referred to as the dual review system. This dual review system separates the scientific assessment of proposed projects from policy decisions about scientific areas to be supported and the level of resources to be allocated, which permits a more objective and complete evaluation than would result from a single level of review. The review system is designed to provide NIH officials with the best available advice about scientific and technical merit as well as program priorities and policy considerations.

The review system consists of two sequential levels of review for each application that will be considered for funding. For most grant and cooperative agreement (hereafter referred to as grant) applications, the initial or first level review involves panels of experts established according to scientific disciplines or medical specialty areas, whose primary function is to evaluate the scientific merit of grant applications. These panels are referred to as Scientific Review Groups (SRGs), a generic term that includes both regular study sections and special emphasis panels (SEPs). In some cases, SRGs in scientifically related areas are organizationally combined into Initial Review Groups (IRGs).

The second level of review of grant applications is performed by National Advisory Boards or Councils composed of both scientific and lay representatives. The recommendations made by these Boards or Councils are based not only on considerations of scientific merit as judged by the SRG, but also on the relevance of a proposed project to the programs and priorities of NIH. In most cases Councils concur with the SRG recommendation. If a Board or Council does not concur with the SRG's assessment of scientific merit, the Board or Council can defer the application for re-review. Subject to limited exceptions as described in Council operating procedures, unless an application is recommended by both the SRG and the Board or Council, no award can be made.

The first level of review of grant applications, and both levels of review of contract project concepts and contract proposals, are governed by the regulations codified at 42 CFR Part 52h, Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects.

The regulations at 42 CFR Part 52h were last amended in November 1982. We are proposing to revise the regulations to incorporate changes that are required to update Part 52h.

The regulations would be revised to: (1) change the section pertaining to conflict of interest to reflect that non-Federal members of SRGs are not appointed as Special Government Employees and therefore are not subject to the conflict of interest statutes and regulations applicable to Federal employees, and to provide a more practical view of the very complex relationships that occur in the scientific community; (2) clarify the applicability of the peer review rules to the review of grant applications and contract proposals; (3) clarify the review criteria applicable to grant applications; and (4) update references, add or amend definitions as necessary, and make appropriate editorial changes.

The conflict of interest provisions in Sec. 52h.5 define real and apparent conflicts of interest, prohibit or restrict participation in peer review by those who have a conflict of interest, and permit waivers of those restrictions under prescribed conditions that are intended to protect the integrity of the review process. It is expected that the flexibility afforded by the proposed regulations will enhance the recruitment of qualified reviewers without compromising the integrity of the review process.

The proposed changes to Sec. 52h.8 "Grants review criteria" were developed after extensive input from and discussion with the scientific community during 1996-1997 in response to a report entitled "Rating of Grant Applications" that was shared with the scientific community. The report and rating criteria were discussed at four open meetings of the Peer Review Oversight Group, whose members include representatives from the peer review community. That group made recommendations to NIH on review criteria (minutes of these meetings are posted on the NIH homepage, www.nih.gov). There was extensive discussion of how to include the concepts of "innovativeness" and "impact" of the research. After due consideration, the Director, NIH, (Federal Register - Volume 65, Number 184 Page 57133/) decided on the revised review criteria for rating unsolicited research grant applications that were published in the NIH Guide for Grants and Contracts, June 27, 1997. These review criteria have been well received by the research community and by those involved in the review process, who view them as beneficial to the review process.

The proposed Sec. 52h.8 clarifies and rearranges the previous review criteria consistent with the criteria published in the NIH Guide. The term "originality" would be moved from (a) to the new (c) where it becomes "the innovativeness and originality of the proposed research." Criterion (b) would be clarified from "methodology" to "approach and methodology." Criterion (e) would be clarified as "the scientific environment and reasonable availability of resources" instead of only "reasonable availability of resources." The scientific peer review group would assess the overall impact that the project could have on the field in light of the assessment of individual review criteria. In addition, review criterion (f), concerning plans to include both genders, minorities, children and special populations, would be added to reflect current statutes and NIH policies.

Additionally, the authority citation would be amended to reflect the current authorities and Secs. 52h.1, 52h.2, 52h.3, 52h.5, and 52h.10 would be amended to reflect the applicability of the regulations to NIH alone. In accordance with the changes in applicability, references to the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) and the Health Resources and Services Administration (HRSA) would be deleted. Section 52h.2 would be amended to include definitions for several additional terms, and minor editorial changes are proposed for several definitions and Sec. 52h.6.

The following statements are provided for public information. Executive Order 12866

Executive Order 12866 requires that all regulatory actions reflect consideration of the costs and benefits they generate and that they meet certain standards, such as avoiding the imposition of unnecessary burdens on the affected public. If a regulatory action is deemed to fall within the scope of the definition of the term "significant regulatory action" contained in Section 3(f) of the Order, pre-publication review by the Office of Management and Budget's Office of Information

and Regulatory Affairs (OIRA) is necessary. This action was reviewed under Executive Order 12866 by OIRA and was deemed not significant.

Regulatory Flexibility Act

The Department prepares a regulatory flexibility analysis, in accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. chapter 6), if a rule is expected to have a significant impact on a substantial number of small entities. The Principal Deputy Director, NIH, certifies that this proposed rule will not have a significant impact on a substantial number of small entities and that a regulatory flexibility analysis, as defined under the Regulatory Flexibility Act of 1980, is not necessary. Executive Order 13132

Executive Order 13132, Federalism, requires that federal agencies consult with State and local government officials in the development of regulatory policies with federalism implications. The Principal Deputy Director, NIH, reviewed the rule as required under the Order and determined that it does not have any federalism implications. The Principal Deputy Director, NIH, certifies that the changes in the scientific peer review regulations will not have an effect on the States, or on the distribution of power and responsibilities among the various levels of government. Paperwork Reduction Act

This proposed rule does not contain any information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). List of Subjects in 42 CFR Part 52h

Government contracts, Grant programs--health, Medical research.

Dated: August 7, 2000.

Ruth L. Kirschstein, Principal Deputy Director, National Institutes of Health.

For the reasons stated in the preamble, part 52h of title 42 of the Code of Federal Regulations is proposed to be revised to read as set forth below.

PART 52h--SCIENTIFIC PEER REVIEW OF RESEARCH GRANT APPLICATIONS AND RESEARCH AND DEVELOPMENT CONTRACT PROJECTS

Sec.

52h.1 Applicability.

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

52h.12 Applicability of other regulations.

Authority: 42 U.S.C. 216; 42 U.S.C. 282(b) 42 U.S.C. 284 (c)(3); 42 U.S.C. 289a.

Sec. 52h.1 Applicability.

(a) This part applies to:

(1) Applications to the National Institutes of Health for grants or cooperative agreements (a reference in this part to grants includes cooperative agreements) for biomedical and behavioral research; and

(2) Biomedical and behavioral research and development contract project concepts and proposals for contract projects administered by the National Institutes of Health.

(b) This part does 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.

Sec. 52h.2 Definitions.

As used in this part:

(a) Act means the Public Health Service Act, as amended (42 U.S.C. 201 et seq.).

(b) 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 that official and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) Budget period means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

- (d) Close relative means a parent, spouse/domestic partner or son or daughter.
- (e) Contract proposal means a written offer to enter into a contract that is submitted to the appropriate agency official by an individual or non-federal organization which includes, as a minimum, a description of the nature, purpose, duration, and cost of the project, and the methods, personnel, and facilities to be utilized in carrying it out. A contract proposal may be (Federal Register - Volume 65, Number 184 Page 57134) unsolicited by the federal government or submitted in response to a request for proposals.
- (f) Development means the systematic use of knowledge gained from research to create useful materials, devices, systems, or methods.
- (g) Director means the Director of the National Institutes of Health and any other official or employee of the National Institutes of Health to whom the authority involved has been delegated.
- (h) Grant as used in this part, includes cooperative agreements.
- (i) Peer review group means a group of primarily non-government experts qualified by training and experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review, to give expert advice on the scientific and technical merit of grant applications or contract proposals, or the concept of contract projects, in accordance with this part.
- (j) Principal Investigator has the same meaning as in 42 CFR part 52.
- (k) Professional associate means any colleague, scientific mentor, or student with whom the peer reviewer is currently conducting research or other professional activities or with whom the member has conducted such activities within three years of the date of the review.
- (l) Project approach means the methodology to be followed and the resources needed in carrying out the project.
- (m) Project concept means the basic purpose, scope, and objectives of the project.
- (n) Project period has the same meaning as in 42 CFR part 52.
- (o) 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 request for proposals. The request for proposals contains information sufficient to enable all offerors to prepare proposals, and is as complete as possible with respect to: 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; format for cost proposals; and evaluation criteria by which the proposals will be evaluated.
- (p) Research has the same meaning as in 42 CFR part 52.

(q) 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 in the areas of biomedical or behavioral research and/or to use such knowledge and understanding to develop useful materials, devices, systems, or methods.

(r) Scientific Review Group has the same meaning as "peer review group", which is defined in paragraph (i) of this section.

(s) Solicited contract proposal has the same meaning as the definition of "offer" in 48 CFR 2.101.

(t) Unsolicited contract proposal has the same meaning as "unsolicited proposal" in 48 CFR 15.601. Sec. 52h.3 Establishment and operation of peer review groups.

(a) To the extent applicable, the Federal Advisory Committee Act (5 U.S.C. App. 2) and Chapter 9 of the Department of Health and Human Services General Administration Manual \1\ will govern the establishment and operation of peer review groups.

\1\ The Department of Health and Human Services General Administration Manual is available for public inspection and copying at the Department's information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Printing Office, Washington, DC 20402.

(b) Subject to section 52h.5 and paragraph (a) of this section, the Director will adopt procedures for the conduct of reviews and the formulation of recommendations under sections 52h.7, 52h.9 and 52h.10. Sec. 52h.4 Composition of peer review groups.

(a) To the extent applicable, the selection and appointment of members of peer review groups and their terms of service will be governed by Chapter 9 of the Department of Health and Human Services General Administration Manual.

(b) Subject to paragraph (a) of this section, members will be selected based upon their training and experience in relevant scientific or technical fields, taking into account, among other factors:

(1) The level of formal scientific or technical education completed or experience acquired by the individual;

(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) Recognition as reflected by awards and other honors received from scientific and professional organizations; and

(4) The need for the group to have included within its membership experts from various areas of specialization within relevant scientific or technical fields.

(c) Except as otherwise provided by law, not more than one-fourth of the members of any peer review group to which this part applies may be officers or employees of the United States. Being a member of a scientific peer review group does not make an individual an officer or employee of the United States.

Sec. 52h.5 Conflict of interest.

(a) This section applies only to conflicts of interest involving members of peer review groups who are not federal employees. This section does not cover individuals serving on National Advisory Councils or Boards, Boards of Scientific Counselors, or Program Advisory Committees who, if not already officers or employees of the United States, are special Government employees and covered by title 18 of the United States Code, the Office of Government Ethics Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), and Executive Order 11222, as amended. For those federal employees serving on peer review groups, in accordance with 52h.4, the requirements of title 18 of the United States Code, 5 CFR part 2635 and Executive Order 12674, as modified by Executive Order 12731, apply.

(b)(1) A reviewer has a real conflict of interest when that reviewer, or a close relative or professional associate of that reviewer, has an interest in an application or proposal that is likely to bias the reviewer's evaluation of that application or proposal. If such a conflict of interest is acknowledged by a reviewer or determined to exist by review staff, the reviewer must recuse him/herself from the review of the application or proposal, except as otherwise provided in this section.

(i) A reviewer who is a salaried employee, whether full- or part-time, of the applicant institution, offeror, or principal investigator, or is negotiating for such employment, shall generally be considered to have a real conflict of interest with regard to applications/proposals from that organization. However, in large organizations or multi-component organizations there may be circumstances where the components are sufficiently independent that an employee of one component can review an application/proposal from another component without a real or apparent conflict of interest, as determined by the Director.

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(ii) A reviewer will be considered to have a real conflict of interest if he/she:

(A) Has received or could receive a direct financial benefit of any amount deriving from an application or proposal under review; or

(B) Apart from any direct financial benefit deriving from an application or proposal under review, has received, is under contract to receive, or is negotiating to receive from the applicant institution, offeror or principal investigator, an honorarium, fee, or other financial benefit not constituting salary that is valued at \$5000 or more per year. Regardless of the level of financial

involvement, if the reviewer feels unable to provide objective advice, he/she must recuse him/herself from the review of the application or proposal at issue.

(iii) Any financial interest of a close relative or professional associate of the reviewer shall be treated as the reviewer's financial interest and be subject to paragraph (b)(1) of this section. Depending on the nature of the relationship and other pertinent factors, as determined by the review staff, the reviewer must either recuse him/herself from the review of an application or proposal in which a close relative or professional associate of the reviewer has a financial interest, or that application or proposal shall be reviewed by another review group in accordance with paragraph (b)(3) of this section.

(iv) For contract proposal reviews, an individual with a real conflict of interest in a particular proposal(s) is generally not permitted to participate in the review of any proposals responding to the same request for proposals. However, if there is no other qualified reviewer available having that individual's expertise and that expertise is essential to ensure a competent and fair review, a waiver may be granted by the Director to permit that individual to serve as a reviewer of those proposals with which he/she has no conflict, while recusing him/herself from the review of the particular proposal(s) with which he/she does have a conflict of interest.

(2) An appearance of a conflict of interest exists where the government official managing the review (i.e., the Scientific Review Administrator or equivalent) determines, in accordance with this subpart, that the circumstances would cause a reasonable person to question the reviewer's impartiality if he or she were to participate in the review. Any appearance of a conflict of interest should be avoided whenever possible through recusal of the reviewer who has an appearance of a conflict, but is not sufficient grounds for recusal when, in the interest of a competent and fair review, it is documented that there is no real conflict of interest, and the Director determines that: It would be difficult or impractical to carry out the review otherwise; and the integrity of the review process would not be impaired.

(3) When a peer review group meets regularly it is assumed that a relationship among individual reviewers in the group exists and that the group as a whole may not be objective about evaluating the work of one of its members. In such a case, a member's application or proposal shall be reviewed by another qualified review group to ensure that a competent and objective review is obtained.

(4) When a member of a peer review group participates in or is present during the concept review of a contract project that occurs after release of the solicitation, as described under Sec. 52h.10(b), but before receipt of proposals, the member is not considered to have a real conflict of interest as described in paragraph (b)(1) of this section, but is subject to paragraph (b)(2) concerning appearance of conflict of interest if the member is planning to respond to the solicitation. When concept review occurs after receipt of proposals, paragraph (b)(1) applies.

(5) No member of a peer review group may participate in any review of a specific grant application or contract project for which the member has had or is expected to have any other responsibility or involvement (whether preaward or postaward) as an officer or employee of the United States.

(6) In addition to the preceding requirements in this paragraph (b), the Director may determine if other particular situations that arise constitute a conflict of interest and require recusal or other appropriate action.

(c) The Director may waive any of the requirements in paragraph (b) of this section relating to a real conflict of interest if he or she determines that there are no other practical means for securing appropriate expert advice on a particular grant or cooperative agreement application, contract project, or contract proposal, and that the real conflict of interest is not so substantial as to be likely to affect the integrity of the advice to be provided by the reviewer. Sec. 52h.6 Availability of information.

(a) 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. Appendix 2), the Privacy Act (5 U.S.C. 552a), and implementing Department of Health and Human Services regulations (45 CFR parts 5 and 5b).

(b) Meetings of peer review groups reviewing grant applications or contract proposals are closed to the public in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)(4), and 552b(c)(6)) and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2). Documents made available to, or prepared for or by such groups that contain trade secrets or commercial or financial information obtained from a person that is privileged or confidential, and personal information concerning individuals associated with applications or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, are exempt from disclosure in accordance with the Freedom of Information Act (5 U.S.C. 552(b)(4), and 552(b)(6)).

(c) Meetings of peer review groups reviewing contract project concepts are open to the public in accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2) and the Government in the Sunshine Act (5 U.S.C. 552b).

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

(a) Except as otherwise provided by law, 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 that 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 by law, recommendations by peer review groups are advisory only and not binding on the awarding official or the national advisory council or board. Sec. 52h.8 Grants: review criteria.

In carrying out its review under Sec. 52h.7, the scientific peer review group (Federal Register Volume 65, Number 184 Page 57136) shall assess the overall impact that the project could have on the field, taking into account, among other factors:

- (a) The significance of the goals of the proposed research, from a scientific or technical standpoint;
- (b) The adequacy of the approach and methodology proposed to carry out the research;
- (c) The innovativeness and originality of the proposed research;
- (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.

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

(a) Except as otherwise provided by law, 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 and said group has made recommendations concerning the scientific merit of that proposal.

(b) Except to the extent otherwise provided by law, such recommendations are advisory only and not binding on the awarding official. Sec. 52h.10 Contract projects involving solicited contract proposals; matters to be reviewed.

(a) Subject to paragraphs (b) and (c) 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 or advisory council in accordance with this part and said group has made recommendations concerning the scientific merit of said 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 he/she determines that the accomplishment 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 until peer review of the project concept and the proposals have been completed. The request for proposals will indicate 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 recompute 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.

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

(a) In carrying out its review of a project concept under Sec. 52h.10(a) or Sec. 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 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 Sec. 52h.9, the peer review group will take into account, among other factors, those criteria in Sec. 52h.8 which are relevant to the particular proposals.

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

Sec. 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 48, or title 45 of the Code of Federal Regulations.[FR Doc. 00-24242 Filed 9-20-00; 8:45 am]BILLING CODE 4140-01-P