

d. Unfunded Mandates Act

This rule does not impose an enforceable duty among the private sector and, therefore, is not a Federal private sector mandate and is not subject to the requirements of section 202 or 205 of the Unfunded Mandates Act. The District has also found under section 203 of the Act, that small governments will not be significantly and uniquely affected by this rulemaking.

List of Subjects in 33 CFR Part 334

Danger zones, Marine safety, Restricted areas, Waterways.

■ For the reasons set out in the preamble, we are amending 33 CFR Part 334 to read as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS.

■ 1. The authority citation for part 334 continues to read as follows:

Authority: 40 Stat. 266; (33 U.S.C. 1) and 40 Stat. 892; (33 U.S.C. 3)

■ 2. Revise section 334.1220 to read as follows:

§ 334.1220 Hood Canal, Bangor; naval restricted areas.

(a) Hood Canal, Bangor; Naval restricted areas—(1) Area No. 1. That area bounded by a line commencing on the east shore of Hood Canal at latitude 47 deg.46'18" N, longitude 122 deg.42'18" W; thence latitude 47 deg.46'32" N, longitude 122 deg.42'20" W; thence to latitude 47 deg.46'38" N, longitude 122 deg.42'52" W; thence to latitude 47 deg.44'15" N, longitude 122 deg.44'50" W; thence to latitude 47 deg.43'53" N, longitude 122 deg.44'58" W; thence to latitude 47 deg.43'17" N, longitude 122 deg.44'49" W.

(2) Area No. 2. Waters of Hood Canal within a circle of 1,000 yards diameter centered on a point located at latitude 47 deg.46'26" N, longitude 122 deg.42'49" W.

(3) The regulations—(i) Area No. 1. No person or vessel shall enter this area without permission from the Commander, Naval Submarine Base Bangor, or his/her authorized representative.

(ii) Area No. 2. (A) The area will be used intermittently by the Navy for magnetic silencing operations.

(B) Use of any equipment such as anchors, grapnels, *etc.*, which may foul underwater installations within the restricted area, is prohibited at all times.

(C) Dumping of any nonbuoyant objects in this area is prohibited.

(D) Navigation will be permitted within that portion of this circular area

not lying within Area No. 1 at all times except when magnetic silencing operations are in progress.

(E) When magnetic silencing operations are in progress, use of the area will be indicated by display of quick flashing red beacons on the pier located in the southeast quadrant of the area.

(4) Enforcement. The regulations in this subsection shall be enforced by the Commander, Naval Submarine Base Bangor, or his/her authorized representative.

Dated: December 29, 2003.

Lawrence A. Lang,

*Deputy Chief, Operations Division,
Directorate of Civil Works.*

[FR Doc. 04-88 Filed 1-2-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

42 CFR Part 52h

RIN 0925-AA

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

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

ACTION: Final rule.

SUMMARY: The National Institutes of Health (NIH) is revising the regulations governing scientific peer review of research grant applications and research and development contract projects and project 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 necessary to update the regulations.

EFFECTIVE DATE: This final rule is effective on February 4, 2004.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, NIH, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852, 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. This dual

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 speciality 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 recommendations. 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 rereview. 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 revising the regulations to incorporate changes that are necessary to update part 52h.

We are revising the regulations to: (1) Clarify the section pertaining to conflict of interest to reinforce the fact that non-Federal members of SRGs are not

appointed as Special Government Employees (SGEs) and therefore are not subject to the conflict of interest statutes and regulations applicable to Federal employees; in practical terms, this means that institutional conflicts as defined for SGEs do not automatically create conflicts of interest for peer reviewers; (2) provide a more practical view of the very complex relationships that occur in the scientific community; (3) clarify the applicability of the peer review rules to the review of grant applications and contract proposals; (4) clarify the review criteria applicable to grant applications; and (5) update references, add or amend definitions as necessary, and make appropriate editorial changes.

We developed the changes to § 52h.8 "What are the review criteria for grants?" 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 at (<http://grants.nih.gov/grants/peer/peer.htm>). There was extensive discussion of how to include the concepts of "innovativeness" and "impact" of the research. After due consideration, the Director of NIH decided on the revised review criteria for rating unsolicited research grant applications that we published in the *NIH Guide for Grants and Contracts (NIH Guide)* on 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.

Section 52h.8 clarifies and rearranges the previous review criteria consistent with the criteria published in the *NIH Guide*. The term "originality" is moved from (a) to the new (c) where it becomes "innovativeness and originality of the proposed research." Criterion (b) is clarified from "methodology" to "approach and methodology." Criterion (e) is clarified as "the scientific environment and reasonable availability of resources" instead of only "reasonable availability of resources." The Scientific Review Group will assess the overall impact that the project could have on the field in light of the assessment of individual review criteria. Additionally, review criterion (f),

concerning plans to include both genders, minorities, children and special populations, is added to reflect current statutes and NIH policies.

Additionally, the authority citation is amended to reflect the current authorities, and §§ 52h.2, 52h.3, 52h.5, and 52h.10 are 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) are deleted. Section 52h.2 is amended to include definitions for several additional terms, and minor editorial changes are made for several definitions and § 52h.6.

In the **Federal Register** of September 21, 2000 (65 FR 57133), NIH published a notice of proposed rulemaking (NPRM), "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects," that provided for a 60-day public comment period. NIH received 13 responses. NIH's consideration of and responses to the comments are discussed below.

Section 52h.4 Composition of Peer Review Groups

In § 52h.4(b) and (b)(4), the phrase "or upon their qualifications as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review" was carried over from the § 52h.2(i) definition of peer review group to provide consistent language about the types of expertise needed to compose a peer review group.

Section 52h.4(c)

The Office of Government Ethics suggested that NIH explain the basis for its conclusion in § 52h.4(c) that members of its peer review groups are not Special Government Employees. A discussion of the statutory and other bases for that conclusion follows.

Pursuant to the Public Health Service (PHS) Act, as amended by the Health Research Extension Act of 1985, the Secretary of Health and Human Services (Secretary), acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of applications for grants, cooperative agreements and contracts for biomedical and behavioral research. Section 402(b)(6), PHS Act, as amended, provides that the Director of NIH can establish peer review groups without regard to Title 5 U.S.C. It is further stipulated (section 492, PHS Act, as amended (42 U.S.C. 289a)) that such review is to be conducted in a manner

consistent with the system for technical and scientific peer review applicable on November 20, 1985. On that date, and for many years prior, peer reviewers were not appointed as or considered to be Federal employees because this peer review was supported through an extramural award mechanism. As directed by the statute, this method of conducting peer review has continued since November 20, 1985.

In fact, the NIH process for peer review has varied little since its inception approximately 50 years ago. Members of the scientific research community have been selected for service on peer review groups, either as members for a specified period of time or on an ad hoc basis from time to time, on a per diem basis but not under the Civil Service (*e.g.*, not as Special Government Employees). There are no appointment papers prepared. These individuals are identified by the Federal employees who oversee the peer review process, the Scientific Review Administrators (SRAs). The SRAs identify potential peer review group members primarily through their knowledge of researchers in the various applicable scientific fields. The make-up of these peer review groups may be up to one-fourth Federal employees (§ 52h.4(c)), such as NIH intramural scientists, but in practice, historically approximately only 1 percent of peer reviewers are Federal employees. Other than the Federal employee reviewers (who cannot be paid any amount in excess of their salaries), peer reviewers are reimbursed through an extramural award mechanism for their services. The reimbursement includes a payment for actual expenses (transportation, room, and board) plus a modest consultant fee for the period of time they are involved in the review of applications at meetings, commonly held in the Bethesda, Maryland area.

The conduct of meetings is directed by the chairperson, although the SRA is the Designated Federal Official who must be present during the review of applications to ensure that the reviews are conducted according to regulations, which includes adherence to established review criteria. Although there is no supervisory relationship between the SRA and the peer reviewers, general guidance on the conduct of meetings has been developed over time through an agreement between the Federal employee overseeing the process and the peer reviewers.

Section 52h.5 Conflict of Interest

One commenter noted that § 52h.5 greatly improves upon current language

regarding how these rules apply to non-Federal employees serving on peer review panels, as distinct from other individuals to whom separate Federal regulations apply. Section 52h.5(a) was further clarified to state that the conflict of interest section applies only to conflict of interest involving members of peer review groups. Since it applies to all members, the phrase "who are not Federal employees" was deleted.

Section 52h.5(b)

One commenter noted that the distinction in the proposed rule between real and apparent conflicts of interest in § 52h.5(b) is artificial and misleading because a real conflict of interest is limited to financial interests and an apparent conflict of interest would encompass all other personal interests that might bias the reviewer. The commenter proposed a single definition of conflict of interest based on the prospect of a personal advantage to the reviewer, whether financial or nonfinancial. A conflict would exist if that personal advantage is strong enough to pose a realistic probability that the reviewer will not perform an unbiased review. As we understand the comment, a distinction would still be made between a conflict involving a direct financial benefit, from which an automatic recusal from the review would result, and other personal interests, which would result in a recusal only if the Scientific Review Administrator and the reviewers so determined.

In response to this comment, definitions of a real conflict of interest and the appearance of a conflict of interest are added to the definitions section of the regulation. However, the substance of the definitions is essentially the same as the meaning given those terms, respectively, in § 52h.5(b)(1) and § 52h.5(b)(2) of the proposed rule. The definition of a real conflict of interest makes it clear that a real conflict of interest exists when certain financial interests are present, when the reviewer acknowledges the presence of an interest that would likely bias his/her review, or when the official managing the review determines the reviewer has such an interest. Thus the definition of a real conflict of interest is not limited to financial interests. We have further highlighted the definition of other (nonfinancial) conflicts of interest by adding subpart (3) to the definition of real conflict of interest (§ 52h.2(q)); this also clarifies our expectation about the professionalism of each reviewer to identify real or apparent conflicts of interest known to the reviewer, as suggested by one

comment. The definition of the appearance of a conflict of interest adopts a different test, the perception of a reasonable person regarding the reviewer's impartiality. This would encompass (1) a financial interest that does not meet the threshold for a real conflict of interest and (2) other personal interests that the official managing the review determines are not likely to bias the reviewer's evaluation of the application or proposal but would cause a reasonable person to question the reviewer's impartiality.

The distinction between a real conflict of interest and an appearance of a conflict of interest has important consequences. A reviewer with a real conflict of interest cannot participate in the review unless the Director of NIH determines that (1) the reviewer's interest arises from his/her ties to a component of a large or multicomponent organization that is independent of the component seeking the funding, (2) the Director makes the determination for a contract proposal that the reviewer is the only person available with the requisite expertise and that expertise is essential to ensure a competent and fair review, or (3) the official managing the review determines that the conflict can be obviated by having another review group review the application or proposal. If it is determined that there is an appearance of a conflict of interest, the reviewer must be recused unless the Director determines that it would be difficult or impractical to carry out the review without the reviewer and the integrity of the review process would not be impaired.

It is expected that examples of real and apparent conflicts of interest will be made available to review officials and reviewers through guidance documents noted in § 52h.5(g), but every instance of such conflicts cannot be anticipated. In addition, the application of the regulations will be reviewed periodically with a view toward any changes that would lessen administrative burdens without compromising the integrity of the review process.

Section 52h.5(b)(1)(i) (§ 52h.5(b)(1) in the Final Rule)

One commenter strongly supported the proposed new regulations, including § 52h.5(b)(1)(i), because they broaden the number of scientists who can serve as potential reviewers of a specific application and allow the Director to determine that components of a multicomponent organization are sufficiently independent so that an employee of one component can review

an application/proposal from another component without a real or apparent conflict of interest. The commenter requested that his organization be recognized as analogous to separate campuses within the same university system; this request will be evaluated separately. Section 52h.5(b)(1) is retained and clarified so that it applies, provided that the reviewer has no multicampus responsibilities at the institution that would significantly affect the other component.

Section 52h.5(b)(1)(ii) (Incorporated in § 52h.2(q)(2) in the Final Rule)

There were several comments regarding § 52h.5(b)(1)(ii), which sets \$5,000 for non-salaried direct financial benefit as the threshold for financial conflict of interest. One commenter stated that this is an improvement upon the current regulations by stipulating a threshold limit for honoraria received by a reviewer from an institution submitting a grant or proposal; however, it should be the same as the \$10,000 threshold in 42 CFR 50.603. Another commenter stated that any association with monetary gain within the previous 12 months or within future 12 months could lead to the appearance of conflict, and that the amount proposed is immaterial. Another commenter asked whether the amount would be periodically adjusted for inflation.

We agree to setting the threshold at \$10,000 (the same threshold as in 42 CFR 50.603), and agree that the amount may be adjusted periodically for inflation. Adjustments may be made by the Director, NIH, after public notice and provision for public comment. Furthermore, the definition of "real conflict of interest" in 52h.2(q)(2) has been clarified to include stock holdings. Consequently, the \$10,000 threshold is a conservative one in that (1) it includes *all* sources of financial benefit, such as honoraria, fees and stock holdings, and (2) it includes both currently held assets as well as honoraria and other financial benefits accruing over a 12-month period. In all, these provisions are intended to allow for routine sharing and exchange of scientific information as a result of invitations to speak at seminars, scientific consultations, and similar events that would not automatically be considered a conflict of interest for the reviewer. At the same time, it would relieve excessive administrative burdens for the potential reviewer and NIH staff for reporting low levels of activity by a reviewer. If there was any concern, it could be treated as an apparent conflict of interest.

Section 52h.5(b)(1)(iii) (§ 52h.5(b)(2) in the Final Rule)

We received several comments regarding proposed § 52h.5(b)(1) that the definition of conflict of interest that involved attributing real conflicts of interest of close relatives or professional associates to the reviewer was too broad. It was noted that the reviewer may not reasonably be expected to know all of the financial or nonfinancial interests that a close relative or professional associate has with an organization or other individuals and would not normally ask them about all of their financial or nonfinancial interests. If the reviewer does not know about a particular interest of the professional associate, then it is not clear how this lack of knowledge could bias the reviewer's evaluation of an application or proposal.

We accepted the comments. Accordingly, we modified the new definitions of real and apparent conflict of interest in § 52h.2 to state that the financial or other interests are "known to the reviewer."

Section 52.5(b)(3) (§ 52h.5(d) in the Final Rule)

Two commenters objected to § 52h.5(b)(3), which provides that when a peer review group meets regularly, it is assumed that a relationship among individual members of the group exists that requires review of a member's application or proposal by a different qualified review group. The commenters suggested that this provision is too restrictive, implies that review groups are biased toward one of their own and cannot be objective, disadvantages members, and will cause potential reviewers to refuse service on standing peer review groups.

Such concerns and perceptions are long-standing. Particularly pervasive has been the assumption that members are disadvantaged by the practice of having their applications reviewed by a different review group, a practice that the NIH has followed for many years. To the contrary, all available data indicate that this assumption is not accurate. The Center for Scientific Review, NIH, has published the available data on this issue on its Web site. This information can be accessed at <http://www.csr.nih.gov/reviewmems.htm>. Because the requirement of § 52h.5(b)(3) corrects a perceived conflict of interest without any disadvantage to the reviewer-applicant, we have made no change in response to this comment.

We provide the following as public information.

Executive Order 12866

Executive Order 12866, Regulatory Planning and Review, requires that 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, prepublication review by the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) is necessary. OIRA reviewed this rule and deemed it significant. Therefore, OMB reviewed this rule prior to publication.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. chapter 6) requires that agencies analyze regulatory actions to determine whether they will create a significant impact on a substantial number of small entities. The Secretary certifies that this rule will not have any such impact.

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. We reviewed the rule as required under the Order and determined that it does not have any federalism implications. The Secretary certifies that this rule 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 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: April 25, 2003.

Elias A. Zerhouni,

Director, National Institutes of Health.

Approved: September 16, 2003.

Tommy G. Thompson,

Secretary.

■ For the reasons stated in the preamble, part 52h of title 42 of the Code of Federal Regulations is 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.

52h.2 Definitions.

52h.3 Establishment and operation of peer review groups.

52h.4 Composition of peer review groups.

52h.5 Conflict of interest.

52h.6 Availability of information.

52h.7 What matters must be reviewed for grants?

52h.8 What are the review criteria for grants?

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

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

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

52h.12 Other regulations that apply.

Authority: 42 U.S.C. 216; 42 U.S.C. 282 (b)(6); 42 U.S.C. 284 (c)(3); 42 U.S.C. 289a.

§ 52h.1 Applicability.

(a) This part applies to:

(1) Applications of 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.

§ 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) *Appearance of a conflict of interest* means that a reviewer or close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer or the government official managing the review and would cause a reasonable person to question the reviewer's impartiality if he or she were to participate in the review; the government official managing the review (the Scientific Review Administrator or equivalent) will evaluate the appearance of a conflict of

interest and determine, in accordance with this subpart, whether or not the interest would likely bias the reviewer's evaluation of the application or proposal.

(c) *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.

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

(e) *Close relative* means a parent, spouse, domestic partner, or son or daughter.

(f) *Contract proposal* means a written offer to enter into a contract that is submitted to the appropriate agency official by an individual or nonfederal organization which includes, at 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 unsolicited by the federal government or submitted in response to a request for proposals.

(g) *Development* means the systematic use of knowledge gained from research to create useful materials, devices, systems, or methods.

(h) *DHHS* means the Department of Health and Human Services.

(i) *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.

(j) *Grant* as used in this part, includes cooperative agreements.

(k) *Peer review group* means a group of primarily nongovernment 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.

(l) *Principal investigator* has the same meaning as in 42 CFR part 52.

(m) *Professional associate* means any colleague, scientific mentor, or student with whom the peer reviewer is currently conducting research or other significant professional activities or with whom the member has conducted such activities within three years of the date of the review.

(n) *Project approach* means the methodology to be followed and the resources needed in carrying out the project.

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

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

(q) *Real conflict of interest* means a reviewer or a close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that application or proposal as determined by the government official managing the review (the Scientific Review Administrator, or equivalent), as acknowledged by the reviewer, or as prescribed by this part. A reviewer shall have a real conflict of interest if he/she or a close relative or professional associate of the reviewer:

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

(2) Apart from any direct financial benefit deriving from an application or proposal under review, has received or could receive a financial benefit from the applicant institution, offeror or principal investigator that in the aggregate exceeds \$10,000 per year; this amount includes honoraria, fees, stock or other financial benefit, and additionally includes the current value of the reviewer's already existing stock holdings. The Director, NIH, may amend the dollar threshold periodically, as appropriate, after public notice and comment; or

(3) Has any other interest in the application or proposal that is likely to bias the reviewer's evaluation of that application or proposal. Regardless of the level of financial involvement or other interest, 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. The peer review system relies on the professionalism of each reviewer to identify to the designated government official any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal.

(r) *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.

(s) *Research* has the same meaning as in 42 CFR part 52.

(t) *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.

(u) *Scientific review group* has the same meaning as peer review group, which is defined in paragraph (k) of this section.

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

(w) *Unsolicited contract proposal* has the same meaning as unsolicited proposal in 48 CFR 15.601.

§ 52h.3 Establishment and operation of peer review groups.

(a) To the extent applicable, the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2) and chapter 9 of the DHHS General Administration Manual¹ shall govern the establishment and operation of peer review groups.

(b) Subject to § 52h.5 and paragraph (a) of this section, the Director will adopt procedures for the conduct of reviews and the formulation of recommendations under §§ 52h.7, 52h.9, and 52h.10.

§ 52h.4 Composition of peer review groups.

(a) To the extent applicable, the selection and appointment of members

¹ The DHHS 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. Government Printing Office, Washington, DC 20402.

of peer review groups and their terms of service shall be governed by chapter 9 of the DHHS 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, or upon their qualifications as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review, 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 the 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, or authorities knowledgeable in the various disciplines and fields related to the scientific areas under review.

(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.

§ 52h.5 Conflict of interest.

(a) This section applies only to conflicts of interest involving members of peer review groups. 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) A reviewer with a real conflict of interest must recuse him/herself from the review of the application or proposal, except as otherwise provided in this section.

(1) A reviewer who is a salaried employee, whether full-time or part-time, of the applicant institution, offeror, or principal investigator, or is negotiating for employment, shall be considered to have a real conflict of interest with regard to an application/proposal from that organization or principal investigator, except that the Director may determine there is no real conflict of interest or an appearance of a conflict of interest where the components of a large or multicomponent organization are sufficiently independent to constitute, in effect, separate organizations, provided that the reviewer has no responsibilities at the institution that would significantly affect the other component.

(2) Where a reviewer's real conflict of interest is based upon the financial or other interest of a close relative or professional associate of the reviewer, that reviewer must recuse him/herself, unless the Director provides a waiver in accordance with paragraph (b)(4) of this section.

(3) 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 the reviewer has no conflict, while recusing him/herself from the review of any particular proposal(s) in which there is a conflict of interest.

(4) The Director may waive any of the requirements in paragraph (b) of this section relating to a real conflict of interest if the Director 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.

(c) Any appearance of a conflict of interest will result in recusal of the reviewer, unless the Director provides a waiver, determining that it would be difficult or impractical to carry out the review otherwise, and the integrity of the review process would not be impaired by the reviewer's participation.

(d) 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.

(e) When a member of a peer review group participates in or is present during the concept review of a contract proposal that occurs after release of the solicitation, as described under § 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) of this section, but is subject to paragraph (c) of this section concerning appearance of conflict of interest if the member is planning to respond to the solicitation. When the concept review occurs after receipt of proposals, paragraph (b) applies.

(f) 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 pre-award or post-award) as an officer or employee of the United States.

(g) The Director may periodically issue guidance to the government officials responsible for managing reviews and reviewers on what interests would constitute a real conflict of interest or an appearance of a conflict of interest.

§ 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 by the Freedom of Information Act, as amended (5 U.S.C. 552), the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), the Privacy Act of 1974, as amended (5 U.S.C. 552a), and implementing DHHS regulations (45 CFR parts 5, 5b).

(b) Meetings of peer review groups reviewing grant applications or contract proposals are closed to the public in accordance with sections 552b(c)(4) and 552b(c)(6) of the Government in the Sunshine Act, as amended (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 peer review 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, as amended (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, as amended (5 U.S.C. 552b).

§ 52h.7 What matters must be reviewed for grants?

(a) Except as otherwise provided by law, no awarding official shall award 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 the 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 council or board concerning an application, the application may not be considered by the council or board unless it has been reviewed by the appropriate peer review group, in accordance with the provisions of this part, and the 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.

§ 52h.8 What are the review criteria for grants?

In carrying out its review under § 52h.7, the scientific peer review group shall assess the overall impact that the project could have on the research field involved, taking into account, among other pertinent 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.

§ 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 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.

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