



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Alleged Conflict of Interest and Breach of Confidentiality in VHA's Merit Review Process

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Executive Summary

Within VA's Office of Research and Development (ORD), research proposals are reviewed by a panel of scientists (merit review subcommittee) with specialized expertise in the area of the proposal. Individuals known as primary and secondary reviewers read the proposals in detail and present the proposal along with their recommendations regarding the merit of the proposal to the committee. Proposals receive a score which has a substantial impact on the decision to provide funding for that proposal. The National Institutes of Health (NIH) and the National Science Foundation (NSF) are other Federal agencies with similar processes for reviewing grants, although on a much larger scale. The complainant alleged that six individuals were members of one particular VA merit review subcommittee and several NIH review panels; that all 6 performed or arranged favorable reviews for each others' work; that they violated the confidentiality of the review process by discussing proposals outside the process, and that this resulted in inappropriate funding for research proposals within the VA.

We substantiated that all researchers named in the complaint did serve on both one particular VA merit review subcommittee and multiple NIH committees, that three of the six named researchers recommended each other for service on a VA subcommittee, and that this practice did not violate VA policy. We further found that these six individuals served as primary or secondary reviewers for each others' work in five instances between the years 2000 and 2006. Some of these individuals published together, served on the same committees, and collaborated on various grants. However, VA's policies do not define personal or professional relationships constituting a conflict of interest in terms applicable to peer review and do not specify the extent and nature of ORD's responsibility to identify these conflicts. The Designated Agency Ethics Official exempted merit review subcommittee members from the requirements of annual financial disclosure statements and signed annual ethics statements otherwise required of Special Government Employees. Neither NIH nor NSF granted a similar exemption.

We were unable to substantiate or refute allegations of breaches in confidentiality and inappropriate funding. But, because of the relationships existing among the named researchers, we recommended that the Acting Under Secretary for Health define conflicts of interest and the individuals responsible for identifying them in the merit review process while requiring that ORD personnel and peer reviewers follow conflict of interest and ethical guidelines applicable to all Federal employees; develop a policy defining diversity in scientific expertise among peer review committees; clarify whether current peer review committee members can recommend others for membership; re-examine whether members should be required to file annual financial disclosure statements; and explore options for coordinating review activities with NIH to minimize potential conflicts of interest across both institutions.



DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Acting Under Secretary for Health (10)

SUBJECT: Healthcare Inspection – Alleged Conflict of Interest and Breach of Confidentiality in VHA's Merit Review Process

Purpose

The Department of Veterans Affairs, Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) conducted an inspection to determine the validity of allegations that certain individuals violated Veterans Health Administration's (VHA's) conflict of interest and confidentiality policies in the awarding of research grants through the Merit Review process. For comparative purposes, we have included a discussion of the peer review processes at the National Institutes of Health (NIH) and National Science Foundation (NSF).

Background

Merit Review Program

The Office of Research and Development (ORD) includes in its mission statement the goal of developing researchers and clinical leaders. Located within VHA, ORD administers four different areas of research: (1) Biomedical Laboratory Research and Development (BLR&D), (2) Clinical Sciences Research and Development (CSR&D), (3) Health Services Research and Development (HSR&D), and (4) Rehabilitation Research and Development. ORD also administers a number of funding programs for research proposals from new or relatively inexperienced investigators, such as the Merit Review Entry Program and the Career Development Award Program. VHA's Merit Review Program, the program involved in this inspection, is designed for experienced researchers who can function as independent principal investigators without mentoring. The Merit Review process differs somewhat among the divisions of ORD.

For the BLR&D and CSR&D programs, funding follows the procedures outlined in Manual M-3, Part II, Chapters 4–6.¹ VHA Handbook 1202.1² is intended to revise this manual but was available only in draft form at the time of this inspection. However, because VHA Handbook 1202.1 is published in draft rather than final form, we apply the standards found in M-3 Part II, Chapter 4, commenting where applicable provisions have been revised in the draft version of VHA Handbook 1202.1.

Within ORD, groups of scientists with expertise in specialized areas (Merit Review subcommittees) peer review research proposals involving the same scientific areas. Each member assigns a score based upon scientific merit. Both full members and ad hoc committee members score proposals. Ad hoc members are additional members recruited based upon the number of proposals that must be scored during a given session. The goal is to provide “fair and objective evaluation” with emphasis on a proposal’s scientific and technical merit, budgetary needs, and duration of funding. The manual describes a three-tiered process for review, beginning at the facility level. Prior to consideration by any Merit Review subcommittee, the researcher responsible for the proposal (the principal investigator or PI) must obtain approval from the medical center director and the medical center’s Research and Development Committee. The PI’s initial application to the Merit Review Program must outline all research projects administered by the PI, regardless of funding source. No PI can have more than one Merit Review proposal unless ORD solicits a special set of proposals.

Members serving on the Merit Review Board subcommittees are selected by their peers. Suggestions for membership may be obtained from current members or other experts in the field. The list of nominations for membership is then reviewed by the Board Chairperson and VA Central Office (VACO) VHA officials.

Subcommittee members are expected to evaluate proposals for scientific merit, including the importance of the work, its novelty and originality, the soundness and feasibility of the design, methodological adequacy, and appropriateness of methods for data analysis and resource utilization. Subcommittee members are also expected to consider the competence and level of productivity of PIs. A priority score is assigned, ranging from 10 to 50, with 10 being the best score. Prior to a subcommittee meeting, ORD sends abstracts of all proposals to be reviewed to all members of the subcommittee. The abstracts contain the names of the researchers submitting the proposal. Committee members then select the proposals which they believe they are the most qualified to review.

Each proposal is scored by a primary reviewer and two secondary reviewers. The portfolio manager determines the ultimate assignments of primary and secondary

¹ Manual M-3, Part II, *Medical Research Program*, includes Chapters 4 – *Merit Review Program*, 5 – *Merit Review Council*, 6 – *Merit Review Appeal Process*.

² Draft VHA Handbook 1202.1, *Biomedical Laboratory Research and Development (BLR&D) and Clinical Science Research and Development (CSR&D) Services – Merit Review Award Program*.

reviewers. It is acknowledged that, while primary and secondary reviewers will read the proposals in their entirety and score them, other subcommittee members do not necessarily read all proposals submitted to the subcommittee. The primary and secondary reviewers present their scores to the subcommittee. "Principal investigators submitting merit review applications are encouraged to suggest the names of 2 or more scientists they believe are qualified to review their proposal." These names are then sent to the Assistant Director of Scientific Review rather than being submitted as part of the proposal.

Manual M-3 also addresses potential conflicts of interest that may arise among members of scientific peer review groups. "VHA scientists must inform the Executive Secretary if they are a member of an advisory group that might ordinarily be expected to review their application." Members of the Merit Review subcommittees may not discuss any matters relating to review of specific applications with the applicant nor may applicants contact any member of the group in reference to an application.

After a Merit Review subcommittee assigns a priority score to a proposal, all proposals are then subject to an administrative review by the Merit Review Council, a group composed of VACO officials. This is the third tier in the review process. The Council cannot override a subcommittee's decision to approve or disapprove a proposal, nor can it change the priority score of a research proposal. It usually accepts the recommendations of the Merit Review subcommittee.

"[F]unding decisions are based entirely on the scientific merit of a proposal as determined by the priority score." If the subcommittee disapproves a PI's entire program or if it gives a priority score that excludes a PI from obtaining funding, the PI can then appeal that decision to the VACO Appeals Committee. "The appeals process is designed to uncover factual or scientific errors." It does not address differences in scientific opinion. The Summary Statement of the Merit Review Board's consensus is the only basis for appeal. The Appeals Committee may accept the decision of the Merit Review Board, sustain the appeal and provide a different priority score and level of funding, recommend another review by the same or a different subcommittee, recommend a site visit, or request additional ad hoc reviews. In spring 2006, ORD maintained 25 different Merit Review subcommittees.

NIH Peer Review Process

NIH is the leading health research agency within the Federal government. Located within the Department of Health and Human Services, it is composed of 27 different institutes³ and centers⁴ (referred to collectively as ICs), each devoted to a specific area of

³ There are 20 Institutes, including such organizations as the National Institute on Aging, the National Institute of Mental Health, and the National Eye Institute.

⁴ The seven Centers include the Center for Scientific Review, the National Center for Research Resources, and the NIH Clinical Center.

expertise. The Center for Scientific Review (CSR) coordinates the peer review process, serving as the central point for receipt of all NIH grant applications. Each application is assigned to both an integrated review group (IRG) and to an IC. IRGs are collections of study sections grouped by general area of scientific expertise. After assigning an IC and IRG, a specific study section is then used to evaluate the proposal's scientific merit. Applicants may request a particular study section or IC. This request is considered, but not binding. Proposals may also be assigned to a special emphasis panel, which is a temporary group formed to review applications that require special expertise or that have a conflict with standing review committees. NIH has study section descriptions available on its web site, along with guidelines concerning appropriate subject matter for each study section to evaluate.

For each proposal, certain reviewers in the study section give written critiques. The Scientific Review Administrator (SRA) for each study section determines which members should initially review the application. Before the study section meets, members list all proposals believed to be in the lower half of the group in terms of scientific merit. If all members agree, these proposals are not discussed, although a written critique is provided to the applicant by the assigned reviewers. For those proposals in the top half of all applications, two or three members provide written reviews, and one or two additional members act as discussants. Following a general discussion, all members assign a priority score privately, which is then tabulated by the CSR. The National Advisory Boards or Councils then review the proposals against a background of considerations "including relevance, program goals, and available funds of the institute." This panel consists of scientists and one or more laypersons. In fiscal year (FY) 2004, NIH reviewed more than 40,000 applications for research projects.

When recruiting qualified individuals to review grant applications, NIH requires that candidates "be recognized authorities in their field," as well as PIs on research projects comparable to those being reviewed. While expertise is the paramount consideration, selections are based on other factors, such as the need to balance the level of seniority in the study section and the need for reviewers who can unite disparate areas represented within the same study section to prevent the development of "factions." Potential members are identified through recent scientific literature, scientific meetings, the list of successful grant applicants, present and former study section members and Chairs, major scientific societies, and Institute Advisory Councils. In addition, anyone interested in becoming a member of a study section may submit curriculum vitae directly to the appropriate SRA. While one person cannot serve as a member on more than one study section, he or she can serve as a member on one study section and an ad hoc reviewer on another study section. An individual also may not concurrently function as both study section member and National Advisory Board or Council member.

Annually, after selection of potential permanent study section members, NIH assembles a nomination package. For each nominee, the package includes curriculum vitae, grant

histories, prior review experience, evidence of expertise, and whether validation of specific nominees from independent sources is required. The nomination package then undergoes several levels of review. Nominations must be approved by at least four different NIH officials. If approved, nominations are forwarded to the central NIH Committee Management Office for evaluation. If appropriate, the Director of NIH gives the final signature of approval. Rejection at any level returns the nomination package to the SRA.

NSF Peer Review Process

The NSF is an independent Federal agency created by Congress that is responsible for funding approximately 20 percent of all basic science research conducted at major colleges and universities in the United States. With an annual budget of \$5.5 billion, the NSF is the major Federal funding source for proposals in areas like mathematics and computer science. It is composed of Directorates, each specializing in an area of scientific expertise and reporting to the Director. The National Science Board, a group of 24 preeminent scientists, is responsible for formulating NSF policy and serving as an advisory board to the President and Congress on national issues relevant to science and engineering.

The NSF Directorates process approximately 40,000 grant applications per year, funding about 11,000. A proposal submitted to NSF is initially evaluated by a Program Officer, the NSF employee who arranges for the proposal to be reviewed by individuals with appropriate expertise. Each proposal is reviewed by 3 to 10 independent reviewers, depending upon the mode of review utilized. Proposals may be reviewed by mail only, by mail and by panel discussion, or by panel discussion alone. NSF maintains an electronic database of reviewers; in FY 2004, this database contained about 300,000 names.

“Program officers identify potential reviewers using a variety of sources, including their own knowledge of the discipline, applicant suggestions, references attached to proposals, published papers, scientific citation indexes and other similar databases, and input from mail reviewers, panelists, and visiting scientists.” PIs submitting proposals may suggest the names of qualified individuals to review their proposal and may also suggest individuals who they would prefer did not review their proposal. “In Fiscal Year 2004, 58,000 individuals served on panels, were sent a proposal for mail review, or served in both functions. About 13,000 of these reviewers had never reviewed an NSF proposal before. The reviewers came from all 50 states in addition to the District of Columbia, Guam, and Puerto Rico.”

The Complaint

The overview of VHA, NSF, and NIH, policies and procedures was presented to provide a Federal policy context for the complaint received through our Hotline. An anonymous

complainant contacted the OIG hotline alleging favoritism and conflict of interest in the Merit Review process. Naming six researchers, the complainant maintained that:

- All six individuals were present or former members of a VHA Merit Review subcommittee and/or NIH study section who mutually recommended each other for membership in VHA Merit Review subcommittees and/or NIH study sections.
- All six individuals performed or arranged favorable reviews for each other's research proposals.
- The six named individuals violated the confidentiality of the VHA Merit Review process by discussing proposals outside the formal meetings of the VHA subcommittee and/or NIH study section.
- Violating confidentiality and arranging favorable reviews resulted in recommendations to fund large (that is, high dollar value) VHA Merit Review and NIH grants.

Scope and Methodology

The scope of this inspection report included only the activities of the six researchers named in the complaint and systemic issues of peer review resulting from their role in VHA's Merit Review and NIH's peer review processes. A review of the scientific merit of any proposal submitted to NIH or VHA is expressly beyond the scope of this inspection. The complaint specified no time period in which these events occurred. We therefore chose to review activities from January 2000 to spring 2006 because VHA Merit Review awards typically have a 5-year duration.

We obtained and reviewed numerous VHA documents, including Summary Rating Sheets, rosters for subcommittee meetings for the past 6 years, lists of ad hoc reviewers, conflict of interest statements for the named researchers, subcommittee meeting minutes, correspondence between VHA's ORD and the named researchers, e-mails, data contained within ORD databases, and minutes of the Research Advisory Council. We interviewed named subcommittee members as well as several unnamed subcommittee members, the Deputy Chief Research and Development Officer, a subcommittee portfolio manager, and numerous support staff within ORD.

We examined NSF's policies for comparative purposes. We examined NIH documents, including study section rosters, organizational charts, publicly available information describing NIH's peer review process, grants awarded to the six named researchers, policies regarding document retention, and policies pertaining to membership selection processes for study sections and other NIH committees. We enlisted the assistance of the Department of Health and Human Services, Office of Inspector General for background assistance and for the purpose of obtaining necessary documents. NIH

documentation was reviewed only for the purpose of identifying any potential conflict with actions taken by the named Scientists during the course of their duties as peer reviewers for ORD. The Department of Health and Human Services, Office of Inspector General referred the allegations concerning NIH grants to NIH's Office of Management Assessment for further review.

We conducted the evaluation in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Inspection Results

Issue 1: Alleged Membership and Recommendations for Membership in Multiple Peer Review Committees

The complainant alleged that the six named researchers maintained membership in multiple peer review committees of the NIH and VHA Merit Review systems and that they recommended each other for service on those committees. We substantiated that the named researchers (hereafter referred to as Scientists 1–6) have been members of one particular VHA Merit Review subcommittee and several NIH study sections from calendar 2000 through 2006. We could not substantiate that they recommended each other for membership in NIH study sections, but we did substantiate that at least three of the six named Scientists recommended each other for membership in VHA Merit Review subcommittees. However, VHA policy does not prohibit this activity.

VHA Merit Review Subcommittee Membership

Within the VHA Merit Review Program, the named Scientists held positions as either full members or ad hoc members on one particular subcommittee. In the 2005 sessions for this committee, Scientist 1 worked as a member while Scientists 2, 3, and 6 functioned as ad hoc consultants. In 2004, Scientist 1 was also a member, while Scientists 2 and 3 worked as ad hoc consultants. In 2003, Scientist 5 served as a member of the committee while Scientists 1, 2, and 3 worked as ad hoc reviewers. In 2001 and 2002, Scientist 5 was a member while Scientist 2 functioned as an ad hoc reviewer and then as a member of the committee in spring 2001. Finally, during the fall 2000 session, Scientists 2, 4, and 5 reviewed proposals for the committee. We therefore substantiated that all named Scientists reviewed proposals for one particular VHA Merit Review subcommittee between the years 2000 and 2006.

We also substantiated that at least three of the six named Scientists recommended each other for membership in VHA Merit Review subcommittees. Scientist 5 asked the portfolio manager to nominate Scientist 1 in his place as a member in 2003. Then, while Scientist 1 recommended Scientists 4 and 6 for membership in the subcommittee in 2005, Scientist 6 recommended Scientist 4 for membership in a different VHA peer review committee in 2004. Scientist 2 also recommended that Scientist 6 become a member of

the 2004 subcommittee. Scientist 1 asked to review Scientist 4's work in 2004. On this second VHA subcommittee, Scientist 4 asked to review Scientist 1's work.

Although we substantiated this allegation, we recognize that this practice is not limited to the named Scientists or the subcommittee involved in this inspection, nor does this violate VHA policy. In addition to recommending each other for membership in VHA's Merit Review subcommittees, the named Scientists also recommended other unnamed individuals to serve on the committee. Also unnamed individuals recommended other unnamed individuals for membership during the same time period as well. Existing VHA policy found in Manual M-3, Part II, Chapter 4 expressly allows solicitation of names of new Merit Review members based upon the recommendations of existing members. The final nomination list is then reviewed by the Board Chairperson, personnel in the Program Review Division, and the Director of BLR&D and CSR&D.

VHA Handbook 1202.1 will supersede this policy. It is currently in draft. It states simply that the Committee members "are recruited from VHA medical centers, universities, industry, public and private research foundations, and other Federal and state government agencies." The policy makes no reference to whether existing members may nominate new members to serve on the Merit Review subcommittees. Therefore, the practice of having existing committee members nominate new members does not violate current VHA policy and will not violate policy currently in draft.

NIH Membership

The named Scientists held positions on NIH study section subcommittees and special emphasis panels as described in curriculum vitae obtained from ORD. Scientist 4 reported membership in at least seven different NIH peer review committees between 2000 and 2006. Scientist 2 held memberships in at least three different NIH committees between 1985 and 1995. Scientist 5 reviewed proposals for at least three different study sections between 1988 and 2000. Scientist 3 evaluated proposals through 10 different NIH committees and special emphasis panels between 2001 and 2005. Scientist 6 served on two different NIH study sections, while Scientist 1 reported membership in two different committees between 1999 and 2001.

Issue 2: Alleged Arrangement of Favorable Reviews between Named Scientists

The complainant further alleged that, as a result of maintaining membership and recommending each other for membership in NIH study sections and VHA Merit Review subcommittees, the named Scientists arranged favorable reviews for each other's proposals. We could neither substantiate nor refute that favorable reviews were motivated by relationships that existed between reviewers and PIs submitting proposals. Further, an assessment of the scientific merit of any given proposal is beyond the scope of this review. However, we did consider whether the named Scientists violated

applicable conflict of interest and ethical standards. Relevant VHA policies include conflict of interest provisions and ethical standards applicable to the Merit Review process by virtue of its members standing as either VHA employees or Special Government Employees (SGEs). NIH and NSF maintain their own standards for conflict of interest and ethics in the peer review process, which we reviewed for comparative purposes.

VHA Conflict of Interest and Ethics Policies

Government employees are required to comply with conflict of interest laws, 18 United States Code (U.S.C.) 201 *et seq.*, and regulations 5 Code of Federal Regulation (CFR) Part 2635, *Standards of Ethical Conduct for Employees of the Executive Branch*. These laws and regulations do not specifically address conflicts of interest and other ethics issues in the context of research activities. VHA does have authority to issue policy advising VHA employees how these laws and regulations apply to research.⁵ Under the existing laws and regulations, Government employees involved in research activities are prohibited from participating in matters that could affect their financial interest. Section 2635.101 of the CFR delineates the general principles of Federal ethics rules. Subparagraph (b)(7) prohibits employees from using public office for private gain, and subparagraph (b)(8) requires employees to act impartially and not give preferential treatment to any private organization or individual. Subparagraph (b)(14) states that employees shall avoid any actions creating the appearance that they are violating the law or the ethical standards set forth in the regulations. The standard for determining whether there is an appearance that the law or regulations were violated is from the perspective of a reasonable person with knowledge of the relevant facts. These standards apply to the VHA Scientists and those who are considered SGEs.

Four of the six named Scientists were VHA employees. The remaining two individuals, by virtue of their service on a VHA Merit Review subcommittee, are considered SGEs. In accordance with the VHA Advisory Committee Management Guide, committee members classified as SGEs must also comply with certain Federal ethics requirements. The minutes of the meetings must include statements that the members who are required to file financial disclosure reports also annually reviewed Federal ethics materials.

While SGEs would normally be required to file financial disclosure reports, the Designated Agency Ethics Official (DAEO) can grant exceptions to this rule. In a Memorandum for the Record dated September 18, 1996, the DAEO excluded members of the Merit Review Board from requirements to file confidential financial disclosure forms. The memorandum indicates that studies evaluating the efficacy of specific drugs or

⁵ As a comparison, VHA Directive 1660.3, *Conflict of Interest Aspects of Contracting for Scarce Medical Specialist Services, Enhanced Use Leases, Health Care Resource Sharing, Fee Basis and Intergovernmental Personnel Act Agreements (IPAS)*, provides policy for the application of conflict of interest laws and regulations to contracting and other matters between VHA medical centers and their affiliates.

products are rarely submitted, making it unlikely that financial conflicts of interest could occur.

By not requiring financial disclosure statements, VHA is unable to determine when a reviewer on a committee holds significant financial interests in products or services being investigated under a research protocol submitted to the committee. These statements would also help to define business relationships that might exist between reviewers and researchers submitting proposals by identifying significant areas of mutual investment or business activity. We note that NIH and NSF reviewers are required to submit financial disclosure statements.

In addition, only SGEs required to submit financial disclosure statements are required to annually review Federal ethics materials. Office of General Counsel informed us that SGEs receive a summary of ethics rules prior to their first meeting. The policy does not explicitly require members to certify that they have reviewed the materials prior to their service as a SGE.

ORD was also unable to provide us with any internal policy defining conflict of interest or impartiality for purposes of VHA's Merit Review process. VHA Handbook 1202.1, which is in draft form, states only that "subcommittee members do not participate in review of proposals from their own institutions or proposals from investigators with whom they have a scientific or personal relationship." It does not define scientific or personal relationship, nor does it reference what would constitute the appearance of a conflict of interest. Manual M-3 Part II references the appearance of a conflict of interest only in the situation where a PI attempts to "personally intervene" in the review process.

At committee meetings, portfolio managers distribute a one-page memorandum on confidentiality and conflict of interest in the Merit Review process at meetings of the Merit Review Board. This memorandum contains the following statement:

To avoid conflicts of interest, Subcommittee members may not be present when applications submitted by their own institutions are being discussed. Members should also absent themselves from meetings because of other conflicts of interest or personal considerations.

No definition or examples of conflict of interest are included. ORD supplied us with voting sheets for meetings occurring between 2003 and 2005, which contained certification of confidentiality and no conflict of interest statements. These statements were signed but undated by all named Scientists except Scientist 4. The certification simply stated that the member was not present for subcommittee discussion and did not vote on any proposal with which the member had a conflict. The statement also does not include a definition of conflict of interest. Blank conflict of interest statements and ethics statements forwarded to us as part of a request for Merit Review Committee member orientation materials referenced HSR&D rather than BLR&D or CSR&D. Because the

scope of this inspection report is expressly limited to BLR&D and CSR&D merit review, these documents were not considered.

Within ORD, the portfolio or program manager is charged with tracking conflicts of interest, but this depends on the self-reporting of reviewers. The portfolio manager obtained this information primarily from the curriculum vitae of the named Scientists. ORD supplied us with copies of the curriculum vitae for the named Scientists maintained by the subcommittee's portfolio manager. In some instances, these curriculum vitae were not current, with one dated January 22, 1999, and a second dated May 28, 2004.

According to interviews with ORD officials, beginning with the spring 2006 cycle, the portfolio manager must conduct an internet search on each reviewer for purposes of identifying conflicts of interest or other issues. ORD could not provide us with a written policy covering these requirements. We were told that conflicts for the purposes of VHA Merit Review subcommittees would include recent (within 3 years) co-authorship with a scientist whose proposal is being considered—essentially the standards currently employed by NIH. ORD could not supply a written VHA policy specifying that these situations constituted conflicts of interest for purposes of peer review. We could locate no VHA or ORD policy defining real or apparent conflicts of interest in terms specific to the peer review process.

Therefore we found that VHA's BLR&D and CSR&D current applicable conflict of interest policy: (1) does not define real versus the appearance of a conflict of interest for purposes of peer review; (2) does not define personal or professional relationships in terms applicable to the peer review process, such as collaboration and co-authorship of publications; (3) does not require annual financial disclosure statements and ethics statements to be completed and signed by all members and ad hoc reviewers of the Merit Review committees pursuant to an exception granted by the DAEO; and (4) does not maintain current curriculum vitae for purposes of identifying potential ethical violations or conflicts of interest. This policy also does not reference the additional measures taken by BLR&D and CSR&D staff to ensure that conflicts of interest do not exist, such as internet searches.

Conflict of Interest Policies Applicable to NIH and NSF Peer Review Systems

Because the VHA policies we reviewed did not define conflict of interest in terms specific to the peer review process, we examined comparable policies utilized by NIH and NSF. Federal ethics provisions and conflict of interest statutes apply to NIH and NSF employees, as well as to VHA employees, but NIH and NSF also maintain policies specific to all grant reviewers governing conflict of interest for purposes of peer review.

NIH's policy defines both a "real conflict of interest" and the "appearance of a conflict of interest." A real conflict of interest occurs when the reviewer, or a close relative or professional associate of the reviewer, has a financial or other interest in an application or

proposal that is likely to bias the reviewer's evaluation. The appearance of a conflict of interest exists when the reviewer, or a close relative or professional associate of the reviewer, has a financial or other interest in an application or proposal that would cause a reasonable person to question the reviewer's impartiality. All reviewers are required to certify, under penalty of perjury, that they have disclosed all conflicts of interest.

NIH describes several situations in which a real conflict of interest would exist. First, if the reviewer is employed by or is negotiating for employment with the applicant institution, offeror, or principal investigator, a real conflict of interest exists for purposes of NIH grant review. Likewise, if the reviewer and a close relative, professional associate, standing review group member, person with whom the reviewer has a longstanding disagreement, or the PI are part of the same multi-site or multi-component project, NIH would consider that a real conflict of interest exists, and the reviewer should recuse himself or herself. NIH policy defines close relative as a parent, spouse, sibling, son, daughter, or domestic partner. "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." When a review group member submits a proposal, NIH also considers the review group as a whole to have a conflict of interest for purposes of reviewing that proposal. The rationale for this stems from the idea that a relationship among the standing members exists that might impair objectivity if reviewing the work of another member.

When the appearance of a conflict of interest may exist, the SRA determines whether or not the interest would likely bias the reviewers. If there is an appearance of conflict of interest but insufficient grounds to determine that a real conflict of interest exists, the SRA must document both that there is no real conflict of interest and that there is no practical alternative to obtaining the opinion of the reviewer with the apparent conflict. In addition, NIH committee members are required to file financial disclosure statements and sign annual ethics statements in accordance with the provisions applicable to Federal Advisory Committees and SGEs.

The NSF also maintains detailed conflict of interest policies and also requires its reviewers to complete annual financial disclosure statements. All NSF peer reviewers must complete "NSF Form 1230P," which describes specific conflicts of interest applicable to the peer review process. These situations include current, pending, or previous employment (within the last 12 months) at the researcher's institution; receipt of an honorarium or award from the institution within the last 12 months; ownership of securities of firms involved in the proposal; business or professional partnership; collaboration on a project, book, article, report, or paper within the last 48 months; close personal friendship; or co-editing of a journal, compendium, or conference proceedings within the last 24 months. In addition, any NSF employee, visiting scientist, or SGE

required to file an annual financial disclosure statement is also required to attend annual conflict of interest training.

Real or the Appearance of Conflicts of Interest Among Named Scientists

In order for a conflict of interest to exist, the named Scientists must not only have a conflict but must also vote on each other's proposals. Therefore, we must first consider whether the named researchers reviewed and voted on each others' proposals. The table on the next page shows the submissions from the named researchers (PIs) and their review activities between the fall 2000 and spring 2006 review sessions. Where proposals were also reviewed by individuals not included in the complaint, the reviewer is described as unnamed.

Table 1: Primary and Secondary Reviewers for the Named Scientists' Proposals

<i>Date</i>	<i>PI</i>	<i>Primary Reviewer</i>	<i>Secondary Reviewer 1</i>	<i>Secondary Reviewer 2</i>
Fall 2000	Scientist 6	Scientist 5	Scientist 2	Unnamed
Fall 2001	Scientist 4	Scientist 2	Scientist 5	Scientist 6
Spring 2003	Scientist 1	Scientist 2	Unnamed	Unnamed
Fall 2003	Scientist 5	Scientist 2	Unnamed	Unnamed
Spring 2006	Scientist 4	Unnamed	Scientist 1	Scientist 3
Spring 2006*	Scientist 6	Unnamed	Unnamed	Unnamed

*This represented the revised review schedule. Prior to April 24, 2006, Scientist 3 was scheduled as a secondary reviewer for Scientist 6's proposal.

In the above cases, when a named Scientist presented a proposal, at least one other named Scientist functioned as primary or secondary reviewer for that proposal with the sole exception of the spring 2006 reviewers listed on the revised schedule.

Further, the named Scientists specifically asked to review other named Scientists' work. For example, e-mails from calendar years 2004 through 2006 addressed to the portfolio manager from the named Scientists reveal that Scientist 1 asked to be the primary reviewer for Scientist 4's proposal, while Scientist 3 requested primary or secondary reviewer status for Scientist 4's and Scientist 6's proposals. As previously noted, Scientist 1 asked to review Scientist 4's work in 2004. On a second VHA peer review subcommittee, Scientist 4 asked to review Scientist 1's work after Scientist 1 recommended him for membership in that committee.

Potential Real Conflicts of Interest

Neither requesting to review certain proposals nor scoring each others' work would violate VHA policy unless there is a real or apparent conflict of interest. Review of voting records and submissions to VHA's Merit Review process, however, demonstrated a potential real conflict of interest as defined by NIH. In fall of 2003, Scientist 5 submitted a proposal to the same VHA Merit Review subcommittee after having served as a standing member of that committee since at least spring of 2001. NIH policy considers a standing member of a committee bringing a proposal before the same committee to be a real conflict of interest because of the presumptive relationship between members of a peer review committee. These proposals are generally directed to a different peer review panel within NIH. Neither NSF standards nor VHA policy specifies whether this would constitute a real or apparent conflict of interest. We note that Scientist 5 did not continue to serve on the subcommittee as a standing member after his proposal was reviewed.

NIH also considers it to be a real conflict of interest if the reviewer is a professional associate of the individual submitting a research proposal. NIH specifies that this would include co-authorship of publications within the last 3 years. Since this requirement is less restrictive than the NSF policy, we applied this definition to determine if there was a potential conflict of interest. Scientist 2 reviewed Scientist 6's proposal in fall of 2000. These two Scientists co-authored 27 publications between 1985 and 1990 and are co-editors on a 2006 textbook. However, they had not been co-authors during the 3 years prior to the date when the review occurred. Scientist 1 co-authored 15 publications with Scientist 6 and 56 publications with Scientist 5. While Scientist 5 reviewed Scientist 6's work (see Table 1), Scientist 1 recused himself from voting on the work of Scientists 5 and 6. Scientists 1, 3, and 5 collaborated on a 2005 publication. We could find no publications of Scientist 4 with any other named Scientist listed as a co-author. Therefore, while 5 of the 6 named Scientists published with other named Scientists, we found that none had co-authored publications within 3 years of voting on each others' proposals.

Federal SGE ethics guidelines applicable to NIH, NSF, and VHA suggest that individuals from the same institution may not review each other's grants. Only Scientists 1 and 5 were employed at the same institution at the time of our review. While Scientist 1 served on the named VHA Merit Review subcommittee, Scientist 1 did not review the work of Scientist 5 between 2000 and 2006. While Scientists 2 and 6 worked for the same institution between 1984 and 1988 and co-authored publications during that time, they were not employed by the same institution at the time in which Scientist 2 voted on Scientist 6's work. We therefore found that no two named Scientists were employed by the same institution at the time that they reviewed each others' work.

Appearance of a Conflict of Interest

While we found evidence of only one possible real conflict of interest, we note that the complainant alleged that the named Scientists were arranging favorable reviews for each other across the NIH and VHA peer review systems. We could neither substantiate nor refute that favorable reviews were arranged nor could we determine who reviewed named Scientists' proposals for NIH because of NIH's document retention policies. However, we note that there is at least the appearance of a conflict of interest when one Scientist reviews another's proposal for NIH and then subsequently has their own proposal reviewed by the same individual for VHA. For example, in spring of 2005, Scientist 1 submitted a grant application to an NIH study section utilizing Scientist 4 as a peer reviewer. In spring of 2006, Scientist 4 submitted a proposal to the VHA subcommittee named in the complaint. Scientist 1 reviewed this proposal (see Table 1). While the researchers do not know the names of the primary and secondary reviewers, the reviewers do know the names of the researchers submitting the proposals that are being reviewed.

In addition, the extent and nature of the publication history between the named Scientists may represent the appearance of a conflict of interest. Recognizing that co-authorship may frequently occur among small groups of scientists with specialized expertise, we also reviewed the named Scientists' publication histories for any publications with other members of the named VHA subcommittee. We found that Scientist 6 published with two unnamed members of the 2006 VHA subcommittee but were unable to find any publications that any of the other named Scientists co-authored with unnamed committee members or ad hoc reviewers. The history of co-authorship among the named Scientists, therefore, does not appear typical of all members of the VHA Merit subcommittee involved in this hotline.

NIH Committee Service

In order to evaluate the allegation that named Scientists reviewed each others' NIH grants, as well as VHA Merit Awards, we first determined whether the grants awarded to the named Scientists were reviewed by NIH study sections in which other named Scientists maintained membership. We found six instances in which named Scientists served on NIH study sections, reviewing the work of other named Scientists.

Table 2: Service of Named Scientists on NIH Study Sections

<i>PI</i>	<i>Study Section</i>	<i>Member 1</i>	<i>Member 2</i>	<i>Member 3</i>
Scientist 2	A	Scientist 5	NA	NA
Scientist 1	A	Scientist 5	NA	NA
Scientist 3	B	Scientist 2	Scientist 5	NA
Scientist 5	C	Scientist 2	Scientist 4	Scientist 6
Scientist 1, 6	B	Scientist 2	Scientist 5	NA
Scientist 1, 5	C	Scientist 2	Scientist 4	Scientist 6

In many instances, we also found that the named Scientists' proposals were evaluated by groups that contained none of the named Scientists. For those committees in which the named Scientists served, NIH supplied us with their policy regarding retention of documents. In accordance with this policy, NIH does not retain review sheets or assignment records regarding who functioned as primary or secondary reviewers on a given proposal.

Reviewing NIH policy or compliance with policy is also outside the scope of this inspection report. Therefore we do not address whether or not these individuals should have or did excuse themselves in situations where they served on a committee evaluating the proposal of another named Scientist. We note only that service on the committees through which certain Scientists submitted proposals creates the possibility of a conflict of interest when these same Scientists review each others' proposals within the VHA Merit Review system. Neither ORD's conflict of interest policy nor NIH's policy specifically addresses whether reviewing each others' grants through two different awards systems would constitute a real or apparent conflict of interest.

Issue 3: Alleged Violations of Confidentiality Policies Applicable to the VHA Merit Review Process

The complainant further alleged that the named Scientists violated the confidentiality of VHA's Merit Review process by discussing proposals outside subcommittee meetings. Based upon information obtained during our interviews with subcommittee members, we could neither substantiate nor refute this allegation. For comparative purposes, the following section presents VHA, NIH, and NSF policies on confidentiality.

VHA, NIH, and NSF Confidentiality Policies

VHA's confidentiality policy regarding the Merit Review process is found in a Certification of Confidentiality agreement located at the bottom of the voting sheets and signed by the reviewers. It states:

I understand that under no circumstances should I advise applicants or others of recommendations nor should I discuss the review proceedings outside the Subcommittee meeting.

We were unable to locate any further policy clarifications or explanations within VHA pertaining to confidentiality in the Merit Review process.

In contrast to VHA policy, NIH and NSF policies are more definitive in that they delineate specific confidentiality and non-disclosure rules concerning peer review of research proposals. Anyone reviewing a proposal for NIH agrees to:

- (1) Destroy or return all materials related to the review process;
- (2) Not to disclose or discuss materials associated with the review, their evaluation, or the review meeting with any other individual except as authorized by an NIH official;
- (3) Not to disclose procurement information prior to the award of a contract; and
- (4) Refer all inquiries concerning the review to an appropriate NIH official.

This confidentiality agreement is made under penalty of perjury. NSF Form 1230P, the conflict of interest form, requires panelists to maintain confidentiality in the peer review process. Specifically, panelists are prohibited from disclosing the contents of the proposal to anyone and prevented from disclosing the contents of any review of the proposal.

Alleged Breach of Confidentiality

Because the nature of the complainant's allegations concerning breach of confidentiality revolved around discussions alleged to occur at scientific meetings, we reviewed presentation histories of the named Scientists to determine if there was any evidence that they attended the same scientific meetings, making such conversations possible. We found that the named Scientists did attend numerous scientific meetings together during the years in which they served on Merit Review subcommittees, but we found no evidence that they breached the confidentiality of the Merit Review process.

During the course of our interviews with subcommittee members, Scientist 1 stated that he obtained advice regarding the review of proposals from his mentor, who was then

Scientist 5. However, he denied that this advice was specific to any given proposal. No other subcommittee member interviewed admitted to discussing proposals outside the review process. Because the complainant is anonymous, and we found no other witnesses to these alleged conversations, we could not substantiate the allegation.

Issue 4: Inappropriate Merit Awards Resulting from Peer Review Violations

The complainant further alleged that these inappropriate review activities and breaches of confidentiality resulted in VHA funding for the named Scientists' proposals. The named subcommittee reviewed 21 proposals in fall of 2005 and 20 proposals in spring of 2005. This represented 4.3 percent and 3.7 percent, respectively, of all proposals undergoing merit review at this session. The committee scored 5 percent of all proposals receiving funding in fall 2005 and 3.9 percent of all proposals receiving funding in spring of 2005. Therefore, we found no evidence that research proposals reviewed by the named subcommittee were disproportionately more likely to receive funding.

We found that 5 of the 6 named Scientists submitted proposals and obtained funding through the named subcommittee and other VHA committees between 2000 and 2006. Through the named subcommittee, Scientist 5 received funding following the fall 2003 session, Scientist 1 following the spring 2003 meeting, Scientist 6 following the fall 2000 and fall 2003 sessions, and Scientist 4 obtained funding after the subcommittee met in fall of 2001. Scientist 2 did not submit a proposal to the named subcommittee during that time frame.

We did not substantiate that the review activities of the six named Scientists resulted in inappropriate funding for research proposals through VHA's Merit Review process. With the exception of one case, the named Scientists did not constitute all of the primary and secondary reviewers for a given proposal. In addition, the committee members may choose to disagree with the primary and secondary reviewers requiring re-evaluation of the proposals. All members of the committee document their scores for a given proposal, and these are kept confidential. Therefore, even if a member of the subcommittee had a relationship with a researcher presenting a proposal before the committee, the process provides checks and balances to ensure the integrity of peer review. Therefore, we did not substantiate the allegation that the activities of the six named Scientists resulted in inappropriate funding of Merit Review proposals.

Other Funding Issues

During the course of examining grants obtained by the named Scientists, we determined that one Scientist received a NIH grant through a VHA nonprofit research corporation (NPC) that appeared similar to another grant obtained through the VHA Merit Review system. To evaluate this issue, we reviewed select NIH and VHA funding policies. The named Scientists received NIH funding between 2000 and 2006. This funding primarily occurred in the form of a modular grant. Modular grants allow the investigator to request

total direct costs, not exceeding \$250,000 per year, instead of describing expenditures in detailed and separate budget categories. Beginning on June 1, 1999, NIH applied this type of budgeting to “all competing individual research project grants (R01), small grants (R03) and exploratory/developmental grants (R21).” In most instances, the named Scientists received R01 grants from NIH. “[R]ecipients are required to allocate and account for costs related to their awards by category within their institutional accounting systems,” not to NIH.

NIH grants received by the named Scientists were either administered by the affiliated institutions or, in some instances, by VHA nonprofit corporations. Legislation enacted in 1988 permitted VA medical centers to create VHA-affiliated NPCs for the purpose of providing a flexible funding mechanism. Initially responsible to the directors of the individual medical centers, NPCs came under central oversight with the creation of the VHA Non-Profit Program Office in 2002.

VHA Handbook 1202.1, which is in draft, outlines ORD's policy concerning identification of instances in which NIH funding might overlap VHA funding. “Budget overlap occurs when duplicate or equivalent budget items, such as equipment or salary, requested in the application are already funded, requested in a pending application or provided from another source.” The handbook requires PIs to summarize in a paragraph any scientific overlap between grants. However, the lack of specific itemized budgets for modular grants within NIH inhibits direct comparison between VHA and NIH budgets for potential overlap. Therefore, we were unable to determine from NIH and VHA documents alone whether overlap occurred.

Conclusion

While we did not substantiate the allegation of inappropriate funding, we found several circumstances raising the possibility of the appearance of a conflict of interest among VHA Merit Review subcommittee members. Complicating our review was the absence of a clearly defined VHA policy specifically addressing conflict of interest issues in the Merit Review process. In comparison, NIH does have a policy that addresses examples of conflicts of interest in the peer review process. Although it appears that the NIH policy is given consideration within the VHA system, it is not enforceable.

Merit Review committee members are not by their service on the committee alone required to file financial disclosure statements or complete annual ethics training. There is currently no mechanism to identify individuals reviewing grants for NIH and prevent them from subsequently having their own grants reviewed by the same individuals in the VHA Merit Review process. While researchers submitting proposals do not have access to the names of the primary and secondary reviewers, neither abstracts nor proposals are de-identified before dissemination to the reviewers. In evaluating research, the experience and qualifications of the individual researcher submitting the proposal are

acknowledged factors in the overall scoring. This prevents de-identification of the actual proposals for purposes of avoiding conflicts of interest.

The six named Scientists served on both NIH and VHA subcommittees between 2000 and 2006; in some cases, they recommended each other for membership. They had in some cases co-authored publications, worked at the same institutions, served on the same professional society committees, and collaborated with each other on NIH grants or VHA Merit Awards. In part, these connections may have occurred because of the very specific area in which these individuals performed research. While NIH policy stresses the importance of a representative peer group in terms of experience, areas of expertise, and individuals who can bridge these areas to prevent “factions,” VHA has no comparable policy. This allows at least the appearance of a conflict of interest to arise in the evaluation of research proposals through the Merit Review process.

The peer review process, while not perfect, is the best system devised to date for the reviewing of research proposals because it ensures the evaluation of scientific merit by those most qualified to make those determinations. The peer review process acts as a check on the system even where conflicts may exist. For example, in the scoring of research proposals, the full committee has the authority and the obligation to disagree with primary or secondary reviewers should they believe that the review presented is incorrect. Recognizing that by the nature of limiting the review to a small group of experts, the potential for real or apparent conflicts of interest increases, we made the following recommendations.

Recommendations

The Acting Under Secretary for Health will ensure that the Chief Research and Development Officer:

1. Defines conflict of interest for the purposes of peer reviewing research proposals.
2. Establishes a policy clearly defining the responsibilities of ORD officials and individual Merit Review Board members in identifying potential conflicts of interest.
3. Identifies within policy any specific objectives concerning the maintenance of diversity in scientific expertise and experience among peer review committees.
4. Clarifies whether the intent of the draft of ORD Handbook 1202.1 is to continue to permit standing members of a committee to suggest individuals for membership in that same committee.

5. Requires Merit Review Board members and portfolio managers to comply with applicable Federal employee and SGE ethical standards and conflict of interest policies.
6. Re-examines, together with the Office of General Counsel, whether current conditions continue to warrant granting Merit Review Board members an exception to the requirement of filing annual financial disclosure statements.
7. Explores options for coordinating review activities with NIH to minimize potential conflicts of interest across both institutions.

Comments

The Acting Under Secretary for Health concurred with the recommendations. He stated that VHA has entered into an agreement that will provide both VA and NIH access to data which will aid in minimizing conflicts of interest in coordinating peer review activities. Furthermore, VHA plans to develop a more comprehensive policy to define what constitutes conflict of interest in the merit review process for the VA research community and to provide all merit review board staff and committee members with educational materials on the appropriate ethical standards. The complete text of his comments are available on pages 22–27. We find this implementation plan acceptable and will follow up until actions are complete.

(original signed by:)

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Acting Under Secretary for Health's Comments

**Department of
Veterans Affairs**

Memorandum

Date: November 21, 2006

From: Acting Under Secretary for Health (10)

Subject: OIG Draft Report, Healthcare Inspection – Alleged Conflict of Interest and Breach of Confidentiality in VHA's Merit Review Process
Project No. 2006-01961-HL-0580, (WebCIMS 366378)

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report, and I concur with the recommendations to limit the potential for real or apparent conflicts of interest in Veterans Health Administration's (VHA's) merit review process. Maintaining the integrity of the Department of Veterans Affairs' (VA's) merit review process is vital in the mission to advance the health care of veterans through collaborative research studies.

2. The Office of Research and Development (ORD) recognized the appropriateness of coordinating review activities with the National Institutes of Health (NIH) prior to your review. ORD and NIH are currently conducting joint reviews of proposals submitted to joint VA/NIH program announcements. VA has also entered into an agreement to use the software systems used to support NIH merit review activities. The adoption of this system will provide both VA and NIH access to data, which will aid in minimizing conflicts of interest in coordinating peer review activities.

3. I agree that VHA's current policy is insufficient in defining what constitutes conflict of interest in the merit review process. The Director of the Biomedical Laboratory Research and Development and Clinical Sciences Research and Development will work to develop a more comprehensive policy for the VA research community. In addition, all merit review board staff and committee members will be provided with educational materials on the appropriate ethical standards, for compliance.

4. Thank you for the opportunity to review the draft report. If you have any questions, please contact Margaret M. Seleski, Director, Management Review Service (10B5) at (202) 565-7638.

(original signed by:)

Michael J. Kussman, MD, MS, MACP

Action Plan in Response to: OIG Draft Report, Healthcare Inspection, Alleged Conflict of Interest and Breach of Confidentiality in VHA's Merit Review Process (WebCIMS 366378)

Project No.: 2006-01961-HL-0580

Date of Report: October 5, 2006

Recommendations/ Actions	Status	Completion Date
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Recommended Improvement Action 1a: The Acting Under Secretary for Health will ensure that the Chief Research and Development Officer defines conflict of interest for the purposes of peer reviewing research proposals.

Concur

The VHA Office of Research and Development (ORD) concurs that the current definition of conflict of interest is insufficiently precise. The Director of Biomedical Laboratory Research and Development (BLR&D) and Clinical Sciences Research and Development (CSR&D) will develop a more comprehensive definition, to be implemented through Standard Operating Procedures within the BLR&D and CSR&D Services. These standard operating procedures shall be communicated via memorandum to the VA research community by the Director of BLR&D and CSR&D and the Chief Research and Development Officer.

In process

February 15, 2007

Recommended Improvement Action 1b: The Acting Under Secretary for Health will ensure that the Chief Research and Development Officer establishes a policy clearly defining the responsibilities of VHA Office of Research and Development (ORD) officials and individual merit review board members in identifying potential conflicts of interest.

Concur

Clarification of the responsibilities of ORD officials and individual merit review board members to identify potential conflicts of interest will be implemented through appropriate changes to the ORD draft policy 1202.1, Standard Operating Procedures, used by BLR&D and CSR&D Services, and related instructions.

In process

February 15, 2007

Recommended Improvement Action 1c: The Acting Under Secretary for Health will ensure that the Chief Research and Development Officer identifies within policy any specific objectives concerning the maintenance of diversity in scientific expertise and experience among peer review committees.

Concur

The maintenance of diversity in scientific expertise and experience is directly relevant to the potential for conflict of interest. While the goal is to assure fair and accurate scientific review by qualified scientific reviewers, it should also be possible through the implementation of operating procedures regarding conflict of interest to achieve both objectives. Operational changes will be implemented through changes to the Standard Operating Procedures used by the BLR&D and CSR&D Services.

In process

February 15, 2007

Recommended Improvement Action 1d: The Acting Under Secretary for Health will ensure that the Chief Research and Development Officer clarifies whether the intent of ORD draft policy 1202.1 is to continue to permit standing members of a committee to suggest individuals for membership in that same committee.

Concur

Language in the ORD draft policy 1202.1, Standard Operating Procedures within the BLR&D and CSR&D, will be clarified to permit anyone to suggest individuals for membership on any committee, as it would be inappropriate to exclude members of the public from suggesting participation by other members of the public. This clarification is also consistent with policies of other organizations.

In process

February 15, 1007

Recommended Improvement Action 1e: The Acting Under Secretary for Health will ensure that the Chief Research and Development Officer requires merit review board members and portfolio managers to comply with applicable federal employee and Special Government employee ethical standards and conflicts of interest policy.

Concur

Compliance to ethical standards is already required by 18 U.S.C. § 208 and implementing policy in 5 C.F.R. § 2635.502. The Director, BLR&D and CSR&D, will assure that each staff member and each committee member is provided with educational materials that clearly inform each individual of these appropriate ethical standards prior to their service on a merit review panel. Further, the Director, BLR&D and CSR&D will assure that each portfolio manager and committee member self-certify compliance with every merit review cycle.

On-going

Recommended Improvement Action 1f: The Acting Under Secretary for Health will ensure that the Chief Research and Development Officer re-examines, together with the Office of General Counsel, whether current conditions continue to warrant granting merit review board members an exception to the requirement of filing annual financial disclosure statements.

Concur

The Director, BLR&D and CSR&D, will meet with ethics staff from the Office of General Counsel (OGC) to determine whether current conditions continue to warrant granting merit review board members an exception to the requirement of filing annual financial disclosure statements. A written request for determination will be made to the OGC by December 15, 2006.

In process

December 15, 2006

Recommended Improvement Action 1g: The Acting Under Secretary for Health will ensure that the Chief Research and Development Officer explores options for coordinating review activities with NIH to minimize potential conflicts of interest across both institutions.

Concur

ORD has already examined the advisability of coordinating review activities with NIH. When appropriate, ORD and NIH currently conduct joint reviews of proposals submitted in response to joint program announcements. Because the statutory missions of NIH and VA differ substantially, it would not be generally appropriate to conduct joint reviews of VA applications. However, ORD has determined that use of software systems used to support NIH review activities is in the interest of VA, and

entered into an agreement on July 21, 2006, to facilitate adoption of this system. This system provides access to data that meets the objective of reducing conflicts of interest in peer review. In reaching this agreement with NIH, ORD believes that it has already complied with the intent of this recommendation.

Completed

July 21, 2006

OIG Contact and Staff Acknowledgments

OIG Contact	Andrea Buck, M.D., J.D. 202 565-8305
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