



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Improper Conduct During Merit Review Proceedings

To Report Suspected Wrongdoing in VA Programs and Operations:
Telephone: 1-800-488-8244
E-Mail: vaoiqhotline@va.gov
(Hotline Information: www.va.gov/oig)

Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted a review in response to allegations that a Merit Review Scientific Review Group (SRG) member (Dr. X) violated ethical standards of conduct by approaching other SRG members to seek support for his wife's (Dr. Y) research proposal. The purpose was to determine whether the allegations had merit.

We substantiated that Dr. X violated ethical standards of conduct by approaching other SRG members to seek support for his wife's research proposal. Dr. X had a clear conflict of interest in this case yet he repeatedly attempted to influence other SRG members to score Dr. Y's proposal favorably. Dr. X's actions over a period of years, but especially as related to the 2011 SRG meetings, reflect a pattern of disregard for professional and ethical standards of conduct regarding the Merit Review process.

We did not evaluate whether Dr. Y's proposal was inappropriately funded as a result of Dr. X's efforts to secure favorable reviews for her proposal. It would appear possible, however, that his actions could have affected the Merit Review proceedings and thus subsequent funding decisions.

At the time of this review, the Office of Research and Development (ORD) did not have explicit guidance on reporting ethical breaches like those discussed in this report. ORD has since revised its Pre-Review Certification Form so that it specifically prohibits any contact, or attempted contact, between or among SRG members or with any other individual(s) outside of the meeting proceedings. It additionally requires confidentiality of review materials and proceedings, prohibits disclosure to anyone not directly involved in the proposal's review, and requires reporting of improper contacts to SRG officials. While this updated guidance enhances the process, SRG members may still be dissuaded from reporting ethical breaches due to concerns about retaliation.

ORD encourages existing SRG members to recommend other qualified scientists for membership on the SRG. While this practice does not violate VHA policy, it could foster subtle alliances and possible collusion. Although we could not say with certainty whether this practice contributed to the events in this case, there was an *appearance* of impropriety regarding one reviewer.

Even though Dr. X is no longer a permanent member of the VA Merit Review SRG central to this case, he retains a 3-year approval to submit research proposals to VA Merit Review for possible funding. If a proposal from Dr. X were approved, he would be required to accept a 5/8 VA appointment and the substantial salary and benefits package associated with that. However, because Dr. X's pattern of improper conduct compromised the integrity of the Merit Review process, his eligibility for Federal research funding should be reconsidered. Furthermore, it needs to be determined whether

Dr. Y's current funding was appropriately awarded, and whether a competitive or noncompetitive review of her ongoing grant award is necessary.

We recommended that ORD (1) conduct an Administrative Board of Investigation into this matter, and (2) evaluate existing policies and controls related to Merit Review SRG processes.

The Under Secretary for Health concurred with our recommendations and provided an acceptable action plan. We will follow up on the planned actions until they are completed.



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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review in response to allegations that a Merit Review Scientific Review Group (SRG) member violated ethical standards of conduct by approaching other SRG members to seek support for his wife's research proposal. The purpose was to determine whether the allegations had merit.

Background

Merit Review Program Overview

The VA Office of Research and Development (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 the Merit Review Award Program, which is an intramural funding mechanism to support investigator-initiated research conducted by eligible VA investigators at VA medical centers or VA-approved sites. This program is BLR&D and CSR&D's principal mechanism for funding basic, preclinical biomedical and behavioral studies, as well as clinical studies of disorders and diseases of importance to the health of veterans. ORD supports health research at more than 115 VA facilities nationwide.

SRGs are comprised of scientists who review and evaluate research proposals involving their specific areas of expertise. The SRG central to this case (referred to as SRG-C in the remainder of this report) meets twice yearly, with typically 30-33 scientists attending each meeting.

Members serving on SRGs are selected by ORD staff. Suggestions for membership may be obtained from current SRG members or other experts in the field. The list of nominations for membership is then reviewed by the SRG's Scientific Review Officer (SRO) and VHA officials. Some individuals are appointed as "permanent" SRG members and serve a 3-year term during which they regularly attend meetings. Others are appointed ad hoc and serve on a meeting-by-meeting basis.

Proposal Review Process

The SRO is responsible for administrative activities of the SRG. Prior to the meeting, the SRO sends abstracts of the proposals that will be under consideration to all members of the SRG. The abstracts include the names of the researchers who submitted the proposals. SRG members then indicate on a spreadsheet specific proposals that are within their areas of expertise and that they want to review. In the selection of proposals, SRG members also indicate whether they want to be the principal reviewer (referred to as the primary reviewer) or have a less central role (secondary or tertiary reviewer). The SRO makes the final reviewer assignments using the spreadsheets as a guide, but is not bound by the selections made by the SRG members.

The spreadsheet also serves as a means for SRG members to recuse themselves from reviewing certain proposals due to real or potential conflicts of interest. For example, a conflict of interest would exist for a particular SRG member if a proposal to be reviewed was submitted by a relative, by another scientist from their academic institution, or by a colleague with whom they have an ongoing professional relationship (as might be evidenced by co-authorship of scientific papers). The SRO is charged with tracking conflicts of interest.

The SRO assigns each proposal to three reviewers having appropriate expertise to review its scientific merit, with one member designated as the primary reviewer, one as secondary reviewer, and one as tertiary reviewer. Any reviewers who identify a real or perceived conflict of interest with respect to a particular proposal are recused from the review and discussion of that proposal.

Proposals are sent to the SRG members prior to the meeting. The primary, secondary, and tertiary reviewers post their preliminary evaluations in an electronic database several days before the meeting. All SRG members (except those having conflicts of interest with the specified proposal) can access the names of the primary, secondary, and tertiary reviewers as well as their preliminary critiques and scores prior to the actual meeting. During the meeting, the primary, secondary, and tertiary reviewers present their reviews and preliminary scores to the SRG for discussion and consensus regarding a scoring range. While the primary, secondary, and tertiary reviewers are expected to read the proposals in their entirety, other SRG members do not necessarily read all proposals scheduled for review. The average workload for each reviewer serving in a primary, secondary, or tertiary capacity is 5-7 proposals, and SRGs typically review 55-75 proposals during each meeting.

SRG 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. After group discussion, each SRG member assigns a score from 1.0 [best] to 5.0 based on scientific merit. The SRG makes its recommendation based on the

average final score (multiplied by 100), which, along with associated materials, is then reviewed administratively. The BLR&D and CSR&D Directors make final decisions about funding based in part on the subcommittee's recommendations, as well as responsiveness to funding priorities, veteran centricity, and availability of funds.^{1,2}

Applicable Conflict of Interest and Ethics Policies

Government employees are required to comply with Conflict of Interest law, 18 United States Code (U.S.C.) 208 and regulation 5 Code of Federal Regulation (CFR) Part 2635, *Standards of Ethical Conduct for Employees of the Executive Branch*. 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 statutory requirements apply to VA scientists serving on the SRGs, as well as to non-VA scientists who are designated as Special Government Employees (SGEs) based on their SRG service. SGEs are defined as executive branch officers or employees that are “retained, designated, appointed, or employed to perform temporary duties either on a full-time or intermittent basis, with or without compensation, for a period not to exceed 130 days during any consecutive 365-day period.”³

VHA Directive 1200 states, “A VA employee has a conflict of interest when he or she participates personally and substantially through decision, recommendation, giving advice, or other action, in any contract, case, controversy, or other particular matter knowing that he, his spouse, minor child, outside employer, or certain others to which he or she has a connection, has a financial interest in the matter. In research, such a conflict of interest would affect, potentially affect, or create the appearance that it could affect, the design, review, conduct, results, or the reporting of research activities or findings.”⁴

VHA has more explicitly defined the rules for conflict of interest, confidentiality, and non-disclosure for reviewers of Merit Review applications. In the version of its Pre-Review Certification Form in force at the time of the events reported here, VHA outlined five bases for conflicts of interest: employment, financial benefit, personal relationships, professional relationships, or other interests. The form specifically defined conflict of interest in the following ways:

¹ VHA Handbook 1204.01, *Scientific Research and Development Proposals*, December 4, 2008.

² VHA Directive 1200, *Veterans Health Administration Research and Development Program*, July 9, 2009.

³<http://ecfr.gpoaccess.gov>

⁴ VHA Directive 1200.

- A **Conflict of Interest** in scientific peer review exists when a reviewer has an interest in a grant or cooperative agreement proposal that is likely to bias his or her evaluation of it. A reviewer who has a real conflict of interest with a proposal may not participate in its review.
- **Real Conflict of Interest** means a reviewer or a close relative or professional associate of the reviewer has a financial or other interest in a proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that proposal as determined by the [SRO] managing the review, as acknowledged by the reviewer, or as prescribed by 42 CFR 52h (which defines specific circumstances comprising conflicts of interest in scientific peer review of research grant applications by the National Institutes of Health [NIH]).

The form further stated, “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 proposal at issue. The peer review system relies on the professionalism of each reviewer to identify to the [SRO] any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal.”

Before each meeting, SRG members certify that they have read the rules and have disclosed all conflicts of interest related to the proposals scheduled for review. Further, the SRO verbally reviews the conflict of interest, confidentiality, and non-disclosure rules with SRG members on the first day of the meeting.

Allegations

In late March 2012, ORD officials alerted the OIG to irregularities and apparent ethical violations involving an SRG-C member (referred to as Dr. X in the remainder of this report). Dr. X is not a VA employee but served as a SGE in the context of his duties as a permanent member of the SRG-C. Specifically, it was alleged that with respect to four other scientists who served on the SRG-C, Dr. X:

- (1) Approached Scientist 1 during the June 2011 SRG-C meeting and prior to the December 2011 SRG-C meeting asking for a favorable review of his wife’s (Dr. Y’s) proposal. Dr. X had apparent knowledge of confidential information that Scientist 1 was a reviewer of Dr. Y’s proposal during the June 2011 meeting.
- (2) Approached Scientist 2 during the December 2011 SRG-C meeting with apparent knowledge that Scientist 2 was a reviewer of Dr. Y’s proposal during that meeting.
- (3) Approached Scientist 3 [through his department chairperson] several years ago with the request, “If you help my wife’s grant at study section, I’ll help your

grant.” At a later date, Dr. X approached Scientist 3 with a request to help detract from a grant proposal on which Dr. X was a reviewer.

- (4) Called and left messages for Scientist 4 on at least two occasions. One of the messages mentioned Dr. Y’s grant application to another agency.

It was further alleged by Scientist 3 that another SRG-C member, Dr. Z, approached him at the June 2011 meeting and attempted to “coerce” him into supporting a proposal on which they were both reviewers.

Scope and Methodology

We reviewed rosters for both the June and December 2011 SRG-C meetings, Dr. X’s signed conflict of interest forms, correspondence between VHA’s ORD and various SRG-C members, e-mails, proposal abstracts, Federal codes and statutes, VA policies, and other documents relevant to this case. We interviewed all of the SRG-C members who attended one or both of the 2011 meetings (42 individuals), the Deputy Chief Research and Development Officer (CRADO), the SRG-C’s SRO, and both Drs. X and Y. We could not review individual scoring sheets due to ORD’s document non-retention policies. This case was declined by OIG’s Criminal Investigations Division after consultation with the Assistant U.S. Attorney having jurisdiction.

We were unable to corroborate the allegation involving Dr. Z; therefore, we did not address this allegation further. Moreover, we did not evaluate the scientific merit of Dr. Y’s research proposal or compare it to other proposals reviewed at the same meetings as this was beyond the scope of our review.

We conducted the inspection in accordance with the *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Summary of Case

Dr. X and Dr. Y are married and conduct research at the same academic institution. Dr. X was a permanent member of the SRG-C for several years. His appointment expired in June 2012. Dr. Y submitted a Merit Review research proposal that was scheduled for review at the June 2011 SRG-C meeting. In accordance with conflict of interest guidelines, Dr. X recused himself from review of the proposal. He had no official access to the preliminary review materials and was not present in the meeting room during discussion of the proposal. However, he participated in other aspects of the meeting.

During the June 2011 meeting, the primary, secondary, and tertiary reviewers of Dr. Y's proposal were Scientist 5, Scientist 6, and Scientist 1, respectively. Scientist 5's preliminary score was favorable; however, Scientists 6 and 1 gave substantially lower preliminary scores. Ultimately, the proposal did not score well enough to qualify for funding and was returned to Dr. Y for revision.

Dr. Y revised her proposal and it was scheduled for review at the December 2011 SRG-C meeting. Initially, the assigned primary, secondary, and tertiary reviewers were Scientist 5, Scientist 2, and Scientist 7, respectively. Just prior to the meeting, Scientist 7 notified the SRO that he would be unable to attend the meeting due to being out of the country but he still submitted his scores and critiques electronically. On short notice, Scientist 8 was asked to substitute for Scientist 7. Again, Dr. X recused himself from the review of the proposal, had no official access to information related to the review, and was not present in the meeting room during discussion of the proposal.

Scientist 5 assigned a favorable preliminary score, as did Scientist 7, who had submitted his scores electronically. Scientist 8 told us that he disagreed with Scientist 7's score and assigned a less favorable score. Scientist 2 assigned an unfavorable preliminary score. After discussion and scoring by all SRG-C members, Dr. Y's proposal received a score in the fundable range. After a second level of regular administrative review, Dr. Y was awarded a 5-year grant totaling \$1.42M, with a funding start date of October 1, 2012.⁵ As required by policy,⁶ Dr. Y accepted a 5/8 VA appointment at the local VA medical center; her annual VA salary will total \$98,187 (inclusive of benefits). Dr. Y told us that she planned to reduce her effort at the university by a corresponding amount in order to accommodate her new VA responsibilities.

⁵ Funding for FY12 is \$402,426. The requested funds for FY 13, 14, 15 and 16 are \$293,073, \$243,073, \$243,073, and \$243,073, respectively.

⁶ VHA Handbook 1202.01, *Biomedical Laboratory Research and Development (BLR&D) and Clinical Science Research and Development (CSR&D) Services Merit Review Award Program Process*, November 4, 2008.

Issue 1. Scientist's Conduct

We substantiated that Dr. X violated ethical standards of conduct by approaching other SRG-C members to seek support for his wife's research proposal. Specifically, Dr. X reportedly approached Scientists 1, 2, 5, and 6, all of whom were reviewers of the proposal in question. Moreover, four additional SRG-C members reported that Dr. X or a person matching his description (three members could not identify Dr. X by name) approached them before or during one of the 2011 SRG-C meetings to specifically comment about Dr. Y's proposal. For the eight scientists who were approached, details of the contacts are as follows:

- Dr. X approached Scientist 1 in the bathroom during the June meeting (after the scores were posted but before discussion of the proposal) and asked, "Can you agree with the reviewer who gave the highest score?"
- Dr. X knew Scientist 5 was a primary reviewer and approached him during the December meeting asking what he thought of the proposal.
- Dr. X approached Scientist 2 outside the restroom during the December 2011 meeting and said he "needed help" with a proposal.
- Dr. X approached SRG-C member #1 (non-primary/secondary/tertiary reviewer who attended both the June and December meetings) seeking a favorable score on the proposal. At the December meeting, Dr. X told this SRG-C member before the discussion that improvements had been made to the proposal.
- Dr. X approached Scientist 6 at the June meeting and was "campaigning" for the proposal, and tried to convince this SRG-C member that the proposal was good. Dr. X also complained that Scientist 1 had assigned a poor score, which was a detail he should not have known.
- An SRG-C member matching Dr. X's description approached SRG-C member #2 (non-primary/secondary/tertiary reviewer) during a break from the December meeting and asked for support for a "mentee's" proposal that did not receive a good score from one of the reviewers.
- An SRG-C member matching Dr. X's description approached SRG-C member #3 (non-primary/secondary/tertiary reviewer) during a break from the meeting and, referring to Dr. Y's proposal, said something like "Hey, you should take a look at this proposal. It's really good."
- An SRG-C member matching Dr. X's description approached SRG-C member #4 (non-primary/secondary/tertiary reviewer) during the December meeting and asked him/her to vote in favor of the proposal.

We also confirmed the contacts as described in allegations (3) and (4). The events discussed in allegation (3) occurred several years ago and do not directly pertain to Dr. Y's current proposal and funding. However, the contacts appear to support a pattern of disregard for professional and ethical standards of conduct regarding the Merit Review

process. Because we do not know Dr. X's intentions as described in allegation (4), we cannot say whether the attempted contacts were improper.

Dr. X gave a different account of his conduct. During our interview, Dr. X reported that he has been a member of various SRGs for many years and that he understood the rules governing conflicts of interest and ethical responsibilities. He specifically denied: (1) that he ever approached or otherwise discussed his wife's proposal with other SRG-C members at any time or in any context; (2) that he had ever obtained confidential information regarding the review of his wife's proposal to which he should not have had access due to his conflict of interest; and (3) that he attempted to influence the review process. Regarding this last point, he stated, "If I had influence, it [the proposal] would have been funded the first time." He reported having no significant personal relationships (either positive or negative) with other SRG-C members, and could think of no reason why someone would make allegations of improper conduct about him.

Dr. Y disclaimed any knowledge of Dr. X's actions in regard to her grant proposal. She stated that she knew he attended the meetings at which the proposal was reviewed, but that he would be restricted from the meeting room during the discussion and voting due to his conflict of interest, and that she never had any conversation with him about the meetings that was related to the review of her proposal. She stated that although their scientific collaboration has been extensive, to the point that Dr. X has been a coauthor of 30–35 of her 45 total published papers, he was not a co-investigator in the proposed research. She stated that her proposal mainly involves investigation of a specific organic compound. A PubMed search of the scientific literature shows five publications between 2008 and 2012 having the name of this compound in the title or abstract that are jointly coauthored by both Drs. X and Y, and one from 2009 authored by Dr. Y without Dr. X.

Dr. X had been a permanent or ad hoc member of the SRG for many years, and by his own account, knew the professional and ethical expectations related to Merit Review SRG membership. Dr. X, by virtue of his service on a VHA Merit Review SRG, was considered an SGE and was subject to the standards of ethical conduct as described on pages 3-4 of this report.

As noted previously, 5 CFR 2635 subparagraph (b)(7) prohibits employees from using public office for private gain or "for the private gain of friends, relatives, or persons with who they are affiliated in a non-Government capacity..."⁷ In this case, Dr. X used his position on the SRG-C to access, and attempt to influence, other members to support his wife's grant proposal. The immediate private gain would have been Dr. Y's VA salary and benefits, with the accompanying financial and professional security associated with VA employment, as well as Dr. Y's access to and discretion over substantial monetary support for her research. While Drs. X and Y would not have received any other

⁷ www.oge.gov/Laws-and-Regulations/Employee-Standards-of-Conduct. Accessed April 26, 2012

immediate monetary benefit from the \$1.42M in grant funding, Dr. Y would have gained the prestige and benefit to her professional reputation associated with increased research funding and the additional publications deriving from that (that historically have frequently included Dr. X as a coauthor). Such prestige and reputational benefit is a valuable asset in the competitive research arena that ultimately leads to rewards such as academic promotions, conferral of tenure, and related salary increases.

VHA Directive 1200 clearly states that “...there is a conflict of interest when an employee *participates personally and substantially* [emphasis added] through decision, recommendation, giving advice, or other action...knowing that he [or] his spouse...has a financial interest in the matter. In research, such a conflict of interest would affect, potentially affect, *or create the appearance that it could affect* [emphasis added], the design, review, conduct, results, or the reporting of research activities or findings.”⁸ At a minimum, it appeared that Dr. X’s actions could affect the Merit Review proceedings.

Dr. X certified via his signature on the Pre-Review Certification Form that he did not *participate in an evaluation* of any proposal with which he had a conflict. While Dr. X appropriately disclosed the conflict and recused himself from the review of the proposal, it is not clear whether he did so based on a personal, institutional, or collegial relationship. After learning that there was a spousal relationship, several scientists we interviewed questioned the propriety of Dr. X attending the 2-day meeting at all given that his wife’s proposal was scheduled for review. Dr. X’s attendance at the meeting provided him with a real-time opportunity to approach, and potentially influence, other SRG-C members.

Of further concern, Dr. X knew who the reviewers were and apparently knew at least some of the preliminary scores assigned by each. Because Dr. X had disclosed a conflict of interest, he was not given access to these details, which suggests that another SRG-C member or members improperly shared the information with him. Several people we interviewed offered their belief that a faction consisting of a few SRG-C members may be “helping each other out” on proposals, and named Dr. X among others as a member of that faction; however, no one provided any specific evidence to support their contentions. One scientist told us that he believes this type of “campaigning” and support on behalf of certain proposals happens indirectly because “people know each other and share common interests in certain types of [scientific] work.” We did not pursue this issue as it was beyond the scope of our review.

Available guidance at the times of the events in 2011 did not specifically address the confidentiality of SRG member identities in the review process. Guidance has since been updated and the VA Conflict of Interest, Confidentiality, and Non Disclosure Rule notice includes the following statement, “SRG members may not discuss applications outside of

⁸ VHA Directive 1200, *Veterans Health Administration Research and Development Program*, July 9, 2009.

the review meeting proceedings to ensure the confidentiality of reviewer identities and of the overall review process.”

Issue 2. Grant Award

Although not specifically alleged, a possible consequence of Dr. X’s conduct may have been to influence the Merit Review process such that Dr. Y’s proposal was inappropriately funded.

We did not evaluate the scientific merit of Dr. Y’s proposal or whether it would have been funded without Dr. X’s attempts to influence the scores. However, given that Dr. X is a successful and relatively senior investigator, his approaches may have influenced and/or intimidated more junior or otherwise vulnerable members, and thereby affected their scoring. Thus, Dr. X’s actions could have affected the scoring outcome and given an unfair advantage to his wife’s proposal over other proposals.

Dr. X approached or otherwise contacted 8 of the more than 40 SRG-C members we interviewed, including 4 of the 5 individuals (as identified by bold lettering in the table below) who were originally designated as primary, secondary, or tertiary reviewers during the 2011 SRG-C meetings. The fifth of these original reviewers, Scientist 7, was appointed to the SRG-C following Dr. X’s recommendation and had twice volunteered to review Dr. Y’s proposal. The remaining reviewer, Scientist 8, was asked at the last minute to step in and be a substitute reviewer.

Table A

	June 2011	December 2011
<i>Primary</i>	Scientist 5	Scientist 5
<i>Secondary</i>	Scientist 6	Scientist 7* (replaced by Scientist 8)
<i>Tertiary</i>	Scientist 1	Scientist 2

Source: VA OIG

Most of the interviewees felt that SRG-C members would “vote their conscience” and score proposals based on the quality of the science. In addition, SRG-C members may choose to disagree with the primary, secondary, and tertiary reviewers, and the number of voting SRG-C members, usually 30 or more, would dilute the effects of any outlier scores. However, SRG-C members may not read all proposals in their entirety and therefore may depend to some extent on the opinions of the primary, secondary, and tertiary reviewers—in this case, reviewers who were uniformly targets of Dr. X’s approaches.

The Merit Review process is highly competitive, with only 15-20 percent of proposals being funded in any given review cycle. Therefore, Dr. X's potential influence on the process was significant as even a slight scoring advantage could be critical to the funding decision.

Issue 3. Reporting Systems and Controls

ORD officials told us that the conduct exhibited by Dr. X was rare, and that SRG members and grant applicants understand and overwhelmingly abide by the professional and ethical principles of the Merit Review process. While this is probably true, it is nevertheless necessary to have effective reporting systems and controls in place to deal with even occasional instances of unethical or inappropriate conduct. In 2011 when these events occurred, there were Federal codes and regulations prohibiting this type of unethical practice. However, there were no formal VA or Merit Review-level policies or guidelines prohibiting this type of contact or attempts at undue influence by SRG members, nor were there requirements to report alleged misconduct or ethical breaches.

Reporting

A majority of the SRG-C members we interviewed were unaware of any formal requirement to report misconduct, although many did indicate that they would notify the SRO of serious breaches. This approach, however, relies on the individual SRG member to judge the degree of alleged misconduct and then decide whether it merits reporting a professional colleague. In all 10 cases where Dr. X made or attempted to make contact, the SRG-C members reported that they found the contacts to be disconcerting and uncomfortable. Scientist 2 promptly reported his/her concerns to the SRO, followed by reports from three more scientists. The remaining six scientists did not report the improper contacts to the SRO.

Some SRG-C members who were contacted by Dr. X expressed concerns about possible retaliation; specifically, they feared that if they did not support Dr. Y's proposal, Dr. X or one of his [SRG-C] "friends" would not fairly evaluate future proposals they might submit. One reviewer told us that a fellow reviewer was upset about being approached, expressed concern about being "labeled," and questioned whether his/her own proposals would be treated fairly by Dr. X or his SRG-C supporters still on the panel. Another reviewer declined to be involved in the second review of Dr. Y's proposal after being approached by Dr. X during the first review; this reviewer expressed concerns about future retaliation. Another SRG-C member requested that Dr. X be declared in conflict for any reviews of his/her work due to concern about potential bias after he/she rebuffed an approach by Dr. X.

VHA guidance has since been updated and states that "Any contact, or attempted contact, between or among SRG members or with any other individual(s) outside of the meeting proceedings is prohibited and must be reported immediately to the SRO for the meeting.

The applications and associated materials made available to reviewers, as well as the discussions that take place during review meetings, are strictly confidential and must not be disclosed to, or discussed with, anyone who has not been officially designated to participate in the review process, either before or after the review meeting.”

Controls

The research proposals being discussed and considered at VA Merit Review SRGs are scientifically complex and highly specialized. As a result, the pool of scientists who are qualified to evaluate some proposals and offer constructive feedback can be limited. It has long been ORD’s practice to not only permit, but encourage, existing SRG members to recommend other qualified scientists for membership on the SRG. While this practice does not violate VHA policy, it could in certain cases foster subtle alliances and possible collusion.

In this case, Dr. X recommended Scientist 7 to be appointed to the SRG-C. Scientist 7 then volunteered to review Dr. Y’s proposal at both the June and December meetings (which was assigned to him for the second review in December 2011). Scientist 7 posted an outstanding preliminary score and favorable review prior to the December 2011 meeting, which he subsequently was unable to attend. Scientist 7 told us that he did not discuss Dr. Y’s proposal with Dr. X and reported that he only had a “casual” relationship with him as they had served together on an NIH review panel in the past. We noted, however, that Scientist 7 provided inconsistent testimony on this matter during our interview. While we can’t say with certainty that Scientist 7’s review of Dr. Y’s proposal was manipulated, the circumstances surrounding his review *give the appearance* of possible impropriety.

Furthermore, scientific research is an enterprise that depends heavily on the integrity of its practitioners. Scientists are not regulated by any type of professional licensure, nor is there any central repository for collecting information about infractions by scientists. Because of these limitations in the ability to monitor and regulate the professional conduct of scientists like Dr. X, his actions related to the Merit Review process provide a vital index of his scientific integrity that extends to other aspects of his Federal research involvement.

Conclusion

We substantiated that Dr. X violated ethical standards of conduct by approaching other SRG-C members to seek support for his wife’s research proposal. Dr. X had a clear conflict of interest in this case but he repeatedly attempted to influence other SRG-C members to score Dr. Y’s proposal favorably. Dr. X’s actions over a period of years, but specifically related to the 2011 SRG-C meetings, reflect a pattern of disregard for professional and ethical standards of conduct regarding the Merit Review process.

We did not evaluate whether Dr. Y's proposal was funded as a possible result of Dr. X's improper contacts. It would appear, however, that his actions could have affected the Merit Review proceedings and subsequent funding decisions.

At the time of this review, ORD did not have clear guidance on reporting ethical breaches like those discussed in this report. ORD has since updated guidance requiring complete confidentiality of review materials and proceedings from disclosure outside of the meeting room and to anyone not directly involved in the proposal's review. Guidance further requires "Any contact, or attempted contact, between or among SRG members or with any other individual(s) outside of the meeting proceedings is prohibited and must be reported immediately to the SRO for the meeting." While this revision to guidance enhances the process, SRG-C members may still be dissuaded from reporting due to concerns about retaliation.

Because there may be a limited pool of scientists who are qualified to review some scientifically complex and highly specialized proposals, ORD encourages existing SRG members to recommend other qualified scientists for membership on the SRG. This practice does not violate VHA policy, but it could foster subtle alliances and possible collusion. We could not say definitively whether this practice contributed to the breakdown in this case, although there was an *appearance* of impropriety.

Even though Dr. X is no longer a permanent member of the VA Merit Review SRG-C, he retains a 3-year approval to submit research proposals to VA Merit Review for possible funding. If a proposal from Dr. X were approved, he would be required to accept a 5/8 VA appointment and the substantial salary and benefits package associated with that.

Because Dr. X's pattern of improper conduct compromised the integrity of the Merit Review process, ORD needs to evaluate whether: (a) to administratively debar Dr. X from participation in future Federal activities; (b) to revoke his current approval to submit proposals to VA Merit Review for possible funding; (c) Dr. Y's current funding was appropriately awarded; and (d) a competitive or noncompetitive review of Dr. Y's ongoing grant award is necessary.

Recommendations

Recommendation 1: To ensure the integrity of the Merit Review process and the appropriateness of funding Dr. Y's research, we recommend that ORD conduct an Administrative Board of Investigation into Dr. X's actions and their consequent effects on the outcome of the review process, and to take appropriate actions, as indicated.

Recommendation 2: We recommend that ORD consider making modifications to the review process such as: (a) prohibiting SRG members from attending meetings where a spouse's (or immediate family member's) proposal is scheduled for discussion; (b) not posting reviewers' identities prior to the formal SRG group discussion; (c) "blinding"

proposals so that reviewers cannot easily identify the author; and (d) requesting SRG members specify the proposals they are competent to review, but not asking for preferences or selection of primary, secondary, or tertiary reviewer roles.

Comments

The Under Secretary for Health concurred with our recommendations and provided an acceptable action plan. (See Appendix A, pages 15-17, for the Under Secretary's comments.) We will follow up on the planned actions until they are completed.



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

Under Secretary for Health's Comments

**Department of
Veterans Affairs**

Memorandum

Date: February 27, 2013

From: Under Secretary for Health (10)

Subject: Healthcare Inspection–Improper Conduct During Merit Review Proceedings

To: Assistant Inspector General for Healthcare Inspections (54)

1. The VA Office of Inspector General, Office of Healthcare Inspections, conducted a review in response to allegations that a Merit Review Scientific Review Group (SRG) member (Dr. X) violated ethical standards of conduct by approaching other SRG members to seek support for his wife's (Dr. Y) research proposal. The purpose was to determine whether the allegations had merit.

2. As a result of this review, the Office of Healthcare Inspections provided two recommendations. The Office of Research and Development (ORD) has reviewed these recommendations. ORD has provided the attached Action Plan.

3. Should you have additional questions, please contact Karen Rasmussen, Acting Director, Management Review Service, at 202-461-6643, or by email at karen.rasmussen@va.gov.

(original signed by)
Robert A. Petzel

**VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan**

OIG Draft Report, Healthcare Inspection, Improper Conduct During Merit Review Proceedings

Project No.: 2012-02317-HI-0387

Date of Draft: 27 December 2012

Recommendations/ Actions	Status	Completion Date
-----------------------------	--------	--------------------

Recommendation 1: To ensure the integrity of the Merit Review process and the appropriateness of funding Dr. Y's research, we recommend that ORD conduct an Administrative Board of Investigation into Dr. X's actions and their consequent effects on the outcome of the review process, and to take appropriate actions, as indicated.

Concur in Principle **Target Completion Date:** 6/30/13

VHA Response:

The Office of Research and Development (ORD) has reviewed this recommendation with the Office of Research Oversight (ORO). VHA has established that ORD has authority to revoke eligibility for Dr. X to receive VA research funding without the additional administrative burden of an Administrative Board of Investigation. ORD has proceeded with review and has sufficient findings to revoke this eligibility. The two offices will also determine whether it is appropriate to seek federal-wide debarment for Dr. X. ORD will complete a reconsideration of the review process to assess whether the funding decisions with regards to Dr. Y were appropriate.

Recommendation 2: We recommend that ORD consider making modifications to the review process such as: (a) prohibiting SRG members from attending meetings where a spouse's (or immediate family member's) proposal is scheduled for discussion; (b) not posting reviewers' identities prior to the formal SRG group discussion; (c) "blinding" proposals so that reviewers cannot easily identify the author; and (d) requesting SRG

members specify the proposals they are competent to review, but not asking for preferences or selection of primary, secondary, or tertiary reviewer roles.

Concur **Target Completion Date: 6/30/13**

VHA Response:

The Office of Research and Development (ORD) will review the current review process and consider making modifications relevant to conflicts of interest. ORD notes that the NIH eRA Commons/IMPACII system also identifies potential conflicts related to institutional or collaborative reasons and provides another check of conflicts when proposals are assigned for review.

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Acknowledgments	Victoria Coates, LICSW, MBA Alan Mallinger, MD

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and
Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and
Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget

This report is available at www.va.gov