

Guidance for Members of NIH Advisory Councils and Boards Assessing Objectivity

The NIH peer review system is the cornerstone for the NIH extramural research enterprise, and is valued around the world as being one of the best ways to ensure that funding decisions are based on a fair, equitable, informed, and unbiased assessment of the scientific merit of proposed biomedical research. For members of NIH Advisory Councils and Boards, the [Standards of Ethical Conduct for Employees of the Executive Branch](#) are followed in order to manage conflicts of interest that arise from financial interests and transactions. However, other professional situations may cause an objective observer to question the integrity of the Council review.

The guidance below should be considered by NIH staff and Council members when assessing potential disqualifications based on questions about professional or personal objectivity. This guidance does not apply *to en bloc* considerations or conflicts of interest due to financial interests, nor does it cover all situations that might arise.

- Scientific competition. In most cases, investigators working on similar research problems can assess each other's work objectively. However, the Council member should recuse him/herself from evaluating an application or matter that involves a competitor, if objectivity cannot be maintained or could be questioned. Examples that could draw objectivity into question include public arguments, heated editorial comments, or patent disputes.
- Collaboration and consulting. A paid collaboration or consultancy constitutes a conflict of interest. However, managing professional objectivity for situations that involve collaborative and similar relationships but not financial interests is increasingly complex, given the multidisciplinary and collaborative nature of biomedical research. Points to consider include the role of the individual on the application in question, the distance between the Council member and the application or matter that involves the application in question, and the appearance of impropriety. For example, is the Council member listed on an application with a substantial role? Affiliated (close relative, collaborator, etc.) in a real way with an individual who is listed on an application with a substantial role? Or just affiliated based on prior work (Watson/Crick) such that an objective observer would question the integrity of the review?
- Mentor/mentee relationships. In most cases, a three-year time out period after a student or fellow leaves a mentor's laboratory is sufficient to eliminate any real or perceived professional bias, if one were to evaluate the other's application. However, a longer time out period may be warranted, if the mentor and mentee continued collaboration after the student or fellow left the lab or other circumstances, such as ill will, exist.
- Co-authorship. In the era of Big Science, many multi-authored publications do not reflect true research collaboration, but rather the pooling and assessment of data from an entire field of investigators, or other types of publications such as conference reports or review articles. Unless other circumstances exist, a Council member should discuss with the Executive Secretary his or her level of involvement in publications with multiple authors or publications such as conference reports to determine whether a disqualification is in order.

- Reviewing the same application in both levels of peer review. An individual may not serve in both levels of NIH peer review (initial peer review and Advisory Council review) at the same time, in the absence of a waiver from the Office of the Director (OD). Similarly, an individual may not evaluate the same application in both levels of NIH peer review, even if the reviews are asynchronous in time, unless given a waiver from the OD.
- Personal relationships. It is not uncommon for Council members to know the investigators listed on the applications they review, but certain situations may require further assessment. Examples include former spouses, close relatives, and personal friends of the Council member.
- Ongoing professional commitments. Many investigators contribute professional effort on an ongoing basis to institutions other than their home institutions, without financial compensation. For example, an investigator may participate in a recurring lecture or seminar series, serve as a member of a graduate dissertation committee, or mentor a beginning investigator in his or her field. While these arrangements may not require disqualification on the basis of institutional affiliation, the interaction between the Council member and his or her host, contact, or affiliate at the other institution may warrant further examination.

In all cases, the Council member should contact the Executive Secretary of the Advisory Council to discuss any questions concerning disqualifications based on potential loss of objectivity. The case studies that follow are provided as examples.

Case Study 1: Scientific Competition

The editor of a leading scientific journal is excited to see two manuscripts on nuclear architecture arrive at the same conclusion using different approaches. The issue has been a longstanding controversy in the field, with most investigators falling into one of two camps or points of view. To accompany the articles in an upcoming issue, the editor asks Dr. A to write an editorial piece explaining the importance of the findings to the field. Dr. A is pleased to do so, and in his editorial praises the two teams of investigators for producing this revolutionary breakthrough, and asserts that the problem has been solved. Perhaps not coincidentally, this conclusion confirms recent papers from his laboratory and his protégé. Subsequently, investigators from the “other” point of view protest and finally win an opposing editorial in the same journal.

- Dr. A is a member of an IC Advisory Council, and is assigned to an application from one of the investigators whose paper was published with his editorial. Should Dr. A be assigned to this application, and participate in the voting on the application?

The Executive Secretary decided to recuse Dr. A from the discussion of and voting on this application thinking that an unbiased observer may question Dr. A's scientific objectivity, in light of the glowing praise in the editorial and his own interest in this avenue of research.

- If the application were submitted to a Request for Applications, should Dr. A participate in the voting on other applications received for that RFA?

The applications submitted to an RFA are treated equally in terms of considering scientific objectivity. If Dr. A is recused for one application, then he should be recused for all applications submitted to that RFA.

Case Study 2: Scientific Competition

An ongoing scientific question in medical research involves the cryopreservation of biological materials, especially cells and embryos. For several decades, scientists have developed methods to preserve cells employing *rapid nonequilibrium vitrification* (concept A) or *equilibrium freezing* (concept B). Both methods are accepted by scientists and have been shown, depending on the investigators' approach, to result in freezing/thawing success rates that are comparable.

A widely published and accomplished research team submitted a new R01 application that proposes a highly innovative and novel approach using concept A to NIH Institute X and received a border-line fundable score. The Principal Investigator (PI), Dr. S, for this application submitted a letter to Council stating that the review process was influenced by one reviewer on the IRG who strongly believes in concept B, the process not proposed by the PI and his team in this application. A member of the Council for Institute X, Dr. B, is an expert in cryobiology, but also happens to work on and publish studies using the concept B. Dr. B has never been in a public argument with the PI for the R01 under review, nor is there any record of an open dispute or editorial exchange between Dr. B and Dr. S. However, in Dr. S' letter to Council, the reviewer is mentioned as having a professional consulting relationship with Dr. B.

- Does this case constitute a situation that results in questioning the Council member's scientific objectivity?

Not necessarily. The only apparent cause for concern is the letter from Dr. S. Differences in scientific opinion do not necessarily lead to questions about scientific objectivity.

- Does Dr. B have to be recused from attending the review during the Council meeting?

Not necessarily. The Executive Secretary may wish to ascertain Dr. B's level of involvement in the reviewer's research and whether that research is related to the project proposed in the application.

Case Study 3: Collaboration and Consulting

The IC asked Dr. W – a Council member – to be one of the reviewers of a special action to transfer an existing R03 to a foreign institution. Dr. W contacted the IC because she had a prior collaboration with the investigator and had published with her in the past. The relationship might be described as an informal mentoring relationship.

- Should Dr. W vote on the special action that involves the R03?

Possibly. Because Dr. W had not published with the investigator in the last three years and no longer had a relationship with the investigator, the Executive Secretary permitted her to be a reviewer for the special action.

- Are other considerations important in deciding whether Dr. W can vote on the special action?

In this case, the IC balanced the benefit of Dr. W's participation against the risk to the integrity of the Council process. Another consideration was that the criteria were largely about the resources in the foreign institution and the priority of the work. They did not involve an assessment of the candidate's qualities (as a MERIT recommendation would). So that diminished the significance of the prior relationship – though it did not eliminate it from consideration. Finally, the IC assessed whether other Council members might be able to review the action, and decided that she should step aside if she thought her prior relationship would influence her review or appear to influence her review.

Case Study 4: Mentors

A program officer (PO) in your IC wants Council to weigh in on the merits of a well-scored and fundable second competitive renewal application (i.e., a Type 2 for years 11-15) by Dr. M. The PO believes that the Dr. M's performance in the last competitive segment, years 6-10, has not been sufficient. The reviewers were impressed with the work and publications as presented, but these were actually from the Type 1, years 1-5, and the PI did not cover the lack of recruitment, analysis, and manuscript development from the first competitive renewal, years 6-10.

The real expert on the Advisory Council is Dr. E, who was Dr. M's graduate advisor. They published many articles together over the years, including one highly significant piece, but nothing in the last 5 years.

- Is this a cause for concern?

Because some mentor/mentee relationships can be long-lasting and the issue is related to the performance of the PI, the Executive Secretary asked another Council member to review the application.

- What points should the Executive Secretary consider regarding Dr. E commenting on Dr. M's Type 2 application?
 - *Mentor/Mentee relationships can be quite long lasting. Is this the case here?*
 - *The issue at hand is performance. Is Dr. E the only member who can comment?*
 - *How does Dr. E view their professional and personal relationship?*

Case Study 5: Co-authorship

A Council member was assigned to an application that cites several of his publications in the Research Strategy and lists those publications in the Reference section.

- Should the Council member have participated in the review and discussion of this application?

The Executive Secretary determined that the citations were provided as background information and that no collaborative relationship existed between the Council member and the investigators on the application. Therefore, she allowed the Council member to review and discuss the application.

- What if the Council member were acknowledged in a publication that involved the investigators on the application?

Recusal on the basis of acknowledgements would not seem necessary, unless the acknowledgement indicated involvement by the Council member in the project that exceeds the level of professional courtesy. Such professional courtesies might include supplying freely-available reagents to the investigators or demonstrating a technique to a student, which frequently are addressed in acknowledgements rather than co-authorship.

- What if the Council member were listed as a co-author on a publication in the Principal Investigator's Biosketch?

This publication may indicate research collaboration between the Council member and the PI, and an interest in the project on the part of the Council member that exceeds the level of a professional courtesy. Therefore, in deciding whether to recuse the Council member, the Executive Secretary might consider the timing of the publication, the contribution made by the Council member to the work, any ongoing collaboration with the investigators, and the number of co-authors on the paper.

- What if the publication in question were a large meta-analysis of data that included the Council member's summary data?

It is possible that the meta-analysis involves nearly all of the qualified investigators in the field, such that no one investigator – not even the Council member – has any greater interest in the Council review than any other would have. Therefore, in deciding whether to recuse the Council member, the Executive Secretary might consider the availability of other, qualified reviewers and weigh the benefit and potential risk to the integrity of the review process if he were to participate in the review.

- Would the situation be different if the Council member had been contacted for raw data for the meta-analysis, and had been asked to participate in the interpretation of the findings?

If the Council member had participated in the interpretation of the findings, an unbiased observer may question the Council member's objectivity or potential bias in participating in the review of the application. Therefore the Executive Secretary in this case might be prudent to recuse the Council member from review and discussion of this application.

Case Study 6: Reviewing the Same Application in Both Levels of Peer Review

Dr. P is a member of an IC Advisory Council. A year before she joined Council she was a member of the ABC study section and after her term on that panel ended she was occasionally used as an ad hoc reviewer on that and other study sections. Before her first Council meeting Dr. P is contacted by the IC to ask if she would be a reader on two grant applications that scored just outside of the funding zone, but were being proposed by IC staff for payment and needed to be discussed at Council. She quickly looks at the applications and recognizes one of them as an application that had gone to a membership conflict Special Emphasis Panel for the XYZ IRG on which she had served as a reviewer shortly before her appointment to Council. She then looks at the other application and notices that it is an A1 application which had been reviewed in ABC and realizes that the A0 version of this application had been reviewed and discussed some time ago at an ABC meeting she attended when she was a member of that study section. Dr. P phones the Executive Secretary of Council for advice.

- Should Dr. P be a reader and participate in the discussion of the application that was reviewed in the membership SEP in which she participated?

It would certainly seem that she should not. NIH policy states that an individual may not participate in both an application's initial peer review and Council review. The intent of this rule is to avoid "double jeopardy", that is, review of an application by the same individual at both levels of review – initial peer review and Advisory Council review. Since Dr. P participated in the initial peer review of this application, the Council Executive Secretary and Dr. P agreed after a conversation that Dr. P would recuse from this discussion.

- Should Dr. P be a reader and participate in the discussion of the application whose A0 version had been reviewed by ABC when she was a member of that panel?

Although she did not participate in the review of the A1 application which is now before Council, the Executive Secretary might consider her participation in the review of the A0 version and whether it could impact or appear to impact her objectivity regarding the current application. It might be decided that Dr. P needs to be recused from the discussion of this application as well.

Case Study 7: Personal Relationships

After reviewing the list of applications that will be considered by Council at the upcoming meeting, a Council member notes that an application from his former college roommate will be considered. While they have not spoken in 15 years, he has followed his former roommate's career by periodically reading published manuscripts. He remembers fondly what good friends they were in college.

- Does the Council member need to be recused from this application?

Because of the lack of current personal contact between the member and the applicant, the Executive Secretary concluded that reading publicly available literature does not constitute an ongoing relationship and therefore that the member did not need to be disqualified from the application.

- Would the situation be handled differently if the Council member's former spouse had submitted an application that will be considered by Council? The member and the applicant had two children together, but the children are now grown, so the member and the applicant no longer share any joint financial obligations.

Despite the lack of financial ties, the Executive Secretary determined that a lack of objectivity might exist between the member and the applicant because of their former marriage and their continued relationship through their children.

- Would the situation change if an application were submitted by a former colleague of one of the Council members? Very early in their careers, the member and the applicant were collaborators, but that relationship ended many years ago. Their research interests have now diverged and they no longer research in the same or even related areas. They remain personal friends and their families have vacationed together.

The Executive Secretary concluded that the Council member should recuse from the application due to his personal friendship with the applicant. Because the member is not an expert in the science proposed, the Executive Secretary appreciated that the member's disqualification will not affect the quality of the review of the application.

Case Study 8: Ongoing Professional Commitments

Dr. L from the University of X is a member of an IC Advisory Council. A few years ago he was asked by Dr. S of Y University to give a lecture on Recent Findings in Hepatitis Research in a graduate course that Dr. S is putting together. There would be no compensation for this lecture. Dr. L readily agreed as he always enjoys interacting with graduate students. Following the lecture, Dr. L and Dr. S go to the university cafeteria for lunch. Over lunch they discuss scientific issues of mutual interest. The next week Dr. S contacts Dr. L to tell him about the positive feedback he's heard from the students about Dr. L's lecture. He mentions that he is going to offer the course during the next semester and invites Dr. L back to give the same lecture, and Dr. L quickly agrees. It was after the second lecture that Dr. L was appointed to the Advisory Council. It never occurred to Dr. L that there could be any bias concern connected with the lectures he gave recently at Y University.

Over the next couple of years, Dr. L's lecture becomes a regular part of Dr. S's course. The post-lecture lunch becomes a tradition as well and Dr. L and Dr. S develop a friendship around their mutual scientific interests – they often e-mail each other when they see research articles that they think will interest the other.

Before one Council meeting Dr. L is contacted by the IC to ask if he would be a reader on two grant applications that staff members felt needed to be discussed at Council. He quickly looks at the applications which happen both to be from Y University and sees that Dr. S is one of the key personnel on one of them. Dr. L phones the Executive Secretary of Council for advice.

- Should Dr. L be a reader and participate in the discussion of the application that involves Dr. S?

As described, Dr. L's relationship with Dr. S has changed with time and has evolved into a "friendship" that includes regular, though infrequent, periodic scientific discussions. The Council Executive Secretary advised that Dr. L should be recused from this discussion.

- Should Dr. L be a reader and participate in the discussion of the other application from Y University?

Although he does not have the title of Adjunct Professor nor does he receive any compensation, his repeated lectures do provide an ongoing service to Y University. A concern may be that this activity and this ongoing relationship with the University may impact or appear to impact his objectivity on matters concerning Y University, and the Council Executive Secretary may consider this in making a decision. It may be decided that Dr. L needs to be recused from any matters involving Y University.