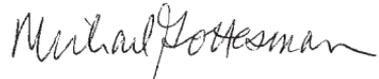


Orientation
Guidelines
for
BOARDS OF
SCIENTIFIC
COUNSELORS

Dear Colleague:

Thank you for agreeing to serve as a member of an NIH Board of Scientific Counselors or an *ad hoc* consultant to an NIH Board of Scientific Counselors. The Intramural Research Program depends on Boards of Scientific Counselors to provide critical review and evaluation of our various research programs. The Board reviews of intramural scientists in which you are about to participate provide an important source of expert outside review. Your input will help us focus our programs on the conduct of distinctive, high-risk, high-impact laboratory and clinical research. Programmatic decisions within the Intramural Research Program rely very heavily on the assessment of the Boards of Scientific Counselors. To help you understand the responsibilities and expectations involved in participating in a Board of Scientific Counselors review,

we have prepared these guidelines, which detail the philosophies, the policies, and the procedures of the review and evaluation. On behalf of the NIH Director, and the Directors and Scientific Directors of the Institutes and Centers, I extend my appreciation for the time and effort required of Board members and *ad hoc* consultants in accomplishing the critical task of evaluating the Intramural Research Program.



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Background

Intramural research at NIH has been subject to external scientific review since 1956, when the first Boards of Scientific Counselors were appointed and charged with the task of evaluating research in the individual Institutes and Centers of the NIH. Since that time, the role of the Boards of Scientific Counselors has evolved to become an integral part of the scientific review process in the Intramural Research Program, codified in law. Most recently, in 1994, based on recommendations of the External Advisory Committee, a subcommittee of the Advisory Committee to the Director, NIH, the policies and procedures for outside scientific review and evaluation of intramural research at NIH by Boards of Scientific Counselors were revised significantly. Subsequent changes to policies and procedures have been made every few years to enhance the process. To improve the rigorous review of each investigator by scientists with the requisite expertise, *ad hoc* consultants are invited to participate along with members of the Boards of Scientific Counselors in reviews or site visits of Intramural Laboratories/Branches/Independent Sections.

This orientation guide describes the goal of the review process, the responsibilities of the participants on the Boards of Scientific Counselors, and the review procedures.

Goal of the Review Process

The goal of the review process is to assist the Scientific Directors by providing a rigorous external scientific review of the Intramural Research Program, including the performance of the intramural scientists and the quality of their research programs.

Intramural research is rarely supported by competitive grants. Priority for research support to intramural scientists is determined by their Scientific Directors based largely on demonstrated scientific accomplishments. Therefore, as recommended in the 1988 report by the Institute of Medicine entitled “A Healthy NIH Intramural Program” and the 1994 Report of the External Advisory Committee, the intramural review process does not adopt the procedures of the extramural competitive grants evaluation. In contrast to the review of extramural grants, which mainly assesses the quality of proposed research, the intramural review evaluates scientists predominantly on the basis of accomplishments since the last review. In the case of a new investigator or one with inconsistent achievements, more emphasis is placed on future plans. The review should evaluate the overall research program of each investigator, for its distinctive quality, impact, and long-term objectives.

The future excellence of the Intramural Research Program depends on the quality of the scientists awarded tenure. Prior to being awarded tenure, the scientist must be evaluated for his/her ability to establish an effective, independent research program and provide high-quality scientific leadership and training within the Intramural Research Program. A scientist is usually considered for tenure after a six-year period as a tenure-track scientist. Eight years are permitted for scientists conducting clinical and population-based research or other long-term projects if approved by the DDIR. During this time, review by the Board of Scientific Counselors usually takes place twice. As one of the initial steps in the review process for tenure, the scientific work of the candidate must be reviewed by the Board. The NIH Central Tenure Committee advises the Deputy Director for Intramural Research on each case, after careful consideration of the Board of Scientific Counselors review of the science, a subsequent Institute tenure panel review, and at least six letters of reference obtained from scientists outside of the Intramural Research Program who are not collaborators. The review by the Board of Scientific Counselors of the merit of the candidate's independent research is a critical element in the tenure process. Final approval of tenure is

granted by the Deputy Director for Intramural Research.

The role of the Scientific Director is to provide the intellectual and administrative leadership of the Intramural Research Program. As described in the Institute of Medicine report, the Scientific Director must have "the qualities of demonstrated scientific achievement, leadership, and administrative ability that are needed for this position." Because the Scientific Director plays such an important role in determining the overall excellence of the Intramural Research Program, the performance of the Scientific Director is reviewed every four to six years by an *ad hoc* committee of the Institute or Center's Advisory Council or Board. The report of the *ad hoc* committee is then reviewed by the applicable Advisory Council or Board. Although the Boards of Scientific Counselors do not directly evaluate the scientific and administrative leadership of the Scientific Directors, because such an oversight role might interfere with the Boards' function in assisting the Scientific Directors, the Boards of Scientific Counselors do review any research effort for which the Scientific Directors are directly responsible.

Responsibilities of Board Members and *Ad Hoc* Consultants

The primary responsibility of the Boards of Scientific Counselors is to evaluate and assess the quality of research being conducted within the Laboratory/Branch/Independent Section under review, the accomplishments of the individual scientists, and the leadership of the Laboratory/Branch Chief. Every intramural scientist with independent resources (tenured, tenure-track, senior scientist/senior clinician, some adjunct investigators) must be reviewed and evaluated.

Based on their review, the Boards of Scientific Counselors should provide evaluation and advice on the overall scientific directions of the program and new directions that could be considered, administration of the program, allocation of resources, and tenure actions under consideration.

Boards of Scientific Counselors reviewers must keep all materials received as part of the review and all proceedings during the review process confidential; they should not discuss them with anyone not involved in the Board of Scientific Counselors review process. In addition, reviewers should not communicate directly with investigators other than during the review itself, but should direct all communications through either the Scientific Director or the Board of Scientific Counselors' chair.

All Board members and *ad hoc* consultants must disclose any real or potential conflicts of interest to the Board of Scientific Counselors' Executive Secretary. In addition, scientists being reviewed should be offered the opportunity to provide a short list of individuals, whose reviews they feel might be biased, including an explanation, for consideration by the BSC chair. Since BSC members are Special Government Employees, they are required to complete the Office of Government Ethics (OGE) Form 450, Confidential Financial Disclosure Report. All reviewers, including *ad hocs*, must adhere to conflict of interest and confidentiality requirements by completing a Conflict of Interest and Confidentiality Certification prior to the meeting of the Board of Scientific Counselors or the site visit review. This certification, and the OGE Form 450 if applicable, is reviewed by the BSC's Executive Secretary.

Review Procedures

Composition of Boards.

Boards consist of outside experts with scientific qualifications to serve as authorities in the fields under review; Board members serve terms of up to five years.

Eligibility for Board of Scientific Counselors membership is governed by the Federal Advisory Committee Act, in accordance with DHHS and NIH policy. Members will be asked to provide proof of citizenship and to submit a Confidential Financial Disclosure Report, OGE 450. Further information regarding eligibility requirements is available from the NIH Office of Federal Advisory Committee Policy.

Frequency of Board Meetings.

Boards must meet with sufficient regularity to ensure that each intramural scientist with independent resources is reviewed at least once every four years. In most Institutes, meetings are held two to three times a year.

Review Meetings.

At the discretion of the Scientific Director, the review of each Laboratory/Branch/Independent Section is conducted either during a regular meeting of the Board of Scientific Counselors or by a site visit team. In Institutes where the entire Board reviews each Laboratory/Branch/Independent Section, *ad hoc* consultants participate in the

meeting and assist in the evaluation to assure necessary expertise. *Ad hoc* consultants are selected by the Chair of the Board, with the advice of the Scientific Director, the Institute or Center Director, and other Board members; not more than one-half of the participants at a regular Board meeting may be *ad hoc* consultants. *Ad hoc* consultants provide individual advice but do not vote. In Institutes in which reviews of each individual Laboratory/Branch/Independent Section are conducted by site visit, at least two regular Board members must be present, in addition to the *ad hoc* consultants. The site visit report is forwarded to the Board for a vote by BSC members.

Information Supplied to Reviewers. *Before meeting, each Board reviewer will be supplied with the following:*

For each Laboratory/Branch being reviewed:

- A description of the overall past accomplishments of the Laboratory/Branch/Independent Section since the last review.
- A summary of the organizational structure of the laboratory being reviewed.

- A listing of all personnel, including their position, type of appointment, and grade, including contract service workers.
- Space usage.
- Operating budget; budget allocation procedures vary considerably among the Institutes and Centers.
- Outside contracts, if any.
- Cooperative Research and Development Agreements (CRADAs), if any.

For each scientist being reviewed:

- A current CV and bibliography.
- Copies of up to three important recent manuscripts or publications.
- Progress report on current research, including descriptions of each project, accomplishments since the last review, and a description of future plans. For each research project, a concise, well-articulated progress report of 3 to 5 single-spaced pages (2,500 words) and a description of future plans of 1 to 2 single-spaced pages (1,000 words) should suffice in most cases.

- A summary of the amount of support staff and space that the scientist uses, in addition to information about budget, contracts, and CRADAs.
- A listing of former fellows and their current positions.
- A copy of the most recent prior Board of Scientific Counselors report of the Laboratory/Branch under review is made available at the review.

Review Format. Each Institute and Center develops its own procedures for the organization and structure of Board meetings. However, the Deputy Director for Intramural Research evaluates each Institute and Center's procedures to ensure that uniform NIH standards are met. The use of site visit teams, solicitation of letters of evaluation from outside experts prior to the BSC, and laboratory visits and interviews with laboratory personnel during a BSC visit are variations chosen by some BSCs.

Scientists should be allotted sufficient time to allow for a formal oral presentation and a question-and-answer period in a session that is open, at a minimum, to all members of the Principal Investigator's group and other PIs in the Laboratory or Branch. If possible, Boards of Scientific Counselors should visit the laboratories of scientists under review, to get a sense of the research environment and to interact with personnel not directly under review to allow an evaluation of the quality of mentoring being provided to trainees. After the scientific presentations, meetings shall be held with each investigator being reviewed, without the Scientific Director present, as a way to learn about specific concerns and constraints, prior to the written report.

The Boards of Scientific Counselors shall provide evaluation and advice on scientific direction of the laboratory, on the scientific programs of tenure-track candidates undergoing midterm and final review, resource allocation, specific projects including new areas of development, and other administrative matters. Specifically, evaluations must address eight criteria.

**Criteria for Review of
Intramural Research**

SIGNIFICANCE

Have the investigator's studies addressed important problems? Are the aims of the project(s) being achieved? Is scientific knowledge being advanced, and are the projects affecting the concepts or methods that drive this field?

APPROACH

In general, are the approaches well conceived? When problem areas arose, were reasonable alternative tactics used?

INNOVATION

Do the projects use novel concepts, approaches, or methods? Are the aims original and innovative? Do the projects challenge existing paradigms or develop new methodologies or technologies? Do the studies include high-risk, high-impact projects?

ENVIRONMENT

Is the investigator taking advantage of the special resources and features of the NIH intramural scientific environment or employing useful collaborative arrangements?

SUPPORT

Is the support the investigator received appropriate?

INVESTIGATOR TRAINING

Is the investigator appropriately trained and well suited to carry out the projects being pursued? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

PRODUCTIVITY

Considering the investigator's other responsibilities (e.g., service or administrative), how would you rate his/her overall research productivity?

MENTORING

Is the investigator providing appropriate training and mentoring for more junior investigators?

Recommendations about resources should be as explicit as possible, with a clear indication of which resources (budget, space, and personnel) should remain the same, be increased, or be decreased.

Reporting of Results of Reviews.

- At the completion of the review, an oral summary of the review should be given to the Scientific Director, Institute or Center Director, and Deputy Director for Intramural Research (or their designees). In addition, the Board shall meet with the Laboratory/Branch Chief before adjournment.
- A written report from the Board of Scientific Counselors is to be prepared following the format preferred by the Scientific Director. It is to consist of a narrative critique of the individual investigators and the research program of the Laboratory/Branch/Independent Section. The report is submitted to

the Scientific Director.

In Institutes and Centers that use site visit teams, the report is distributed to all members of the Board of Scientific Counselors. The site visit team report is considered by the entire Board at its next scheduled meeting, and the Board uses the report in developing its advice to the Scientific Director.

- Evaluations of individual investigators must address the quality and impact of the research projects, the validity of the approaches used to address the scientific questions, and the level of resources (space, budget, and personnel) supplied to the investigator. These evaluations should be written by members of the Board and should reflect the majority view; minority views should be included. Each investigator shall receive in a timely fashion his/her evaluation and have the opportunity to provide written comments to the Scientific Director.
- A written report, reviewed by all members of the BSC, is to be sent within two months to the Scientific Director and the Institute or Center Director.

Follow-up. At the next meeting of the Board, the Scientific Director will respond to the report, indicating areas of agreement and disagreement and planned or completed actions. Within six months, the Scientific Director provides the Board with a written response. Copies of both the report and the response are sent to the Institute or Center Director, the Deputy Director for Intramural Research, and the Director, NIH, for further discussion with the DDIR. The Board of Scientific Counselors reports annually to the Institute or Center National Advisory Council or Board, either by endorsing a written report of the Scientific Director, by providing the Board of Scientific Counselors report and Scientific Director's response, or by providing an independent report to be presented to the Council. Because of the sensitive, personal nature of evaluations, recommendations, and follow-up actions, reports of intramural reviews are considered confidential.

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