

**Policies and Procedures to Guide
BOARDS OF
SCIENTIFIC
COUNSELORS
In Reviewing Intramural Research at the NIH**

July 6, 2017

**National Institutes of Health
Office of the Director**

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 diverse research programs and researchers who conduct them. The Board reviews of intramural scientists in which you are about to participate provide an important source of expert outside scientific review. Your work is critical in assuring the excellence of our high quality research programs that focus on improving human health. The approach of the IRP is to form a healthy balance between investigator-driven and collaborative team science in a collegial culture that accommodates world-class basic, translational, population-based, and clinical research. Decisions regarding resource allocation, within the Intramural Research Program rely 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 assembled these guidelines and policies to inform the review and evaluation of intramural research. On behalf of the NIH Director, as well as the Directors, Scientific Directors, and Clinical 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 essential task of evaluating the Intramural Research Program.

Michael M. Gottesman, M.D
*Deputy Director for
Intramural Research, NIH*
July 2017

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 and grown to become an integral part of the scientific review process in the Intramural Research Program, codified in law. 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 and improve the process based on guidance from NIH leadership with input from the Chairs of the Boards of Scientific Counselors. To focus 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 formal reviews or as part of site visits to review intramural scientists with independent resources.

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 Institute and Centers 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 researchers are not eligible to apply for extramural NIH grants, and intramural research is infrequently supported by competitive non-NIH grants, although this is permitted. Priority for research support to intramural scientists is determined by the 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 follow the same process for extramural competitive grants evaluation, which mainly assesses the quality of proposed research. The intramural review evaluates scientists mainly retrospectively on the basis of scientific 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 evaluates the overall research program of each investigator, for its distinctive quality, impact, and long-term objectives. The actual review criteria are the same as those applied to extramural grant applications with the addition of consideration whether the investigator is taking advantage of the special resources and features of the NIH intramural scientific environment.

The future excellence of the Intramural Research Program depends on the quality of its scientists, especially those 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 7-year period as a tenure-track scientist. Nine 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 two to three times. 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 BSC reports on the quality of science and training/mentoring in the laboratory, but does not make a direct recommendation about tenure. The BSC only advises if the tenure-track investigator is “on track” or “not on track” for tenure nomination. 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 by the individual scientists with independent resources. Thus scientists to be reviewed and evaluated include all senior investigators, investigators, senior scientists/senior clinicians, assistant clinical investigators, as well as some adjunct investigators, staff clinicians, and staff scientists depending on their research portfolio.

Based on their review, the Boards of Scientific Counselors should provide evaluation and advice to IC leadership on the overall scientific directions of the program and new directions that could be considered, administration of the program, allocation of resources, and career advancement.

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. The final BSC reports are reviewed by IC Directors and their Council or Board but are not released without approval by the IC. The DDIR must receive all final BSC reviews.

All Board members and *ad hoc* consultants must disclose any real or potential financial or other conflicts of interest, e.g., scientific, to the Board of Scientific Counselors' Executive Secretary for evaluation and assessment by the Scientific Director and ethics officials as needed (see Manual Chapters 1810-1 and 2400-4). 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 (See [The Ethics in Government Act as amended, 5 USC App. and 18 USC 208, with implementing regulations, 5 CFR Parts 2634, 2635, and 2640](#)). 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 a preceding site visit review. This certification, and the OGE Form 450 if applicable, is reviewed by the BSC's Executive Secretary.

BSCs shall be trained to identify and make serious efforts to avoid implicit bias (beliefs) in the review of intramural scientists. Implicit bias applies not only to race and ethnicity, but also other social groups defined by age, physical abilities, religion, sexual orientation, weight, etc. Training modules on implicit bias will be supplied to BSC members, as well as ad hoc consultants, via the BSC Executive Secretaries, who will be charged to include such training on BSC and site visit agendas. Any evidence of bias detected at BSC meetings and /or site visits will be addressed by the chair and necessary corrective action taken.

Review Procedures

Composition of Boards. Boards consist of outside scientific subject matter experts with qualifications to serve as authorities in the fields under review; Board members serve terms of up to five years. [See Manual Chapter 3005 for specific composition.]

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 or Branch is conducted during a regular meeting of the Board of Scientific Counselors and in some cases with the benefit of a preceding site visit team. *Ad hoc* consultants may participate in **Board meetings and site visits** to assist in the evaluation and assure necessary expertise. A diverse group of *ad hoc* consultants is 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 shall not vote. In Institutes in which reviews of each individual Laboratory or Branch are conducted by preceding 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 full Board for review and vote by full BSC members; ad hoc members may not vote.

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.
- Patents and Licenses.
- Clinical Protocols being conducted by the PI's program.

For each scientist being reviewed:

- A current CV and bibliography.
- Copies of up to three important recent manuscripts or publications.
- There is flexibility among ICs to report progress 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 report will conform to review templates developed by the ICs but generally do not exceed 12 pages per project. The emphasis is on past accomplishments with an accompanying briefer description of future plans. Early career PIs or PIs with inconsistent achievements may be asked to provide more information on future plans.
- 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 and solicitation of letters of evaluation from outside experts prior to the BSC are variations chosen by some BSCs. Laboratory visits and interviews with laboratory personnel, including postdoctoral and post baccalaureate fellows during a BSC visit are strongly encouraged so the board members and site visitors can 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.

Scientists should be allotted sufficient time to allow for a formal oral presentation and a question-and-answer period in a session that should be open to all members of the Principal Investigator's group and other PIs in the Laboratory or Branch. This allows members of the laboratory or branch to understand the context and importance of their work and benefit from questions of the reviewers. After the scientific presentations, meetings shall be held with each investigator 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 distinctive 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 is 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 prepared following the format preferred by the Scientific Director. It consists 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 Institute and 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.

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES
Public Health Service
National Institutes of Health