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NATIONAL CANCER INSTITUTE
DIVISION OF CANCER EPIDEMIOLOGY AND GENETICS
REVIEW CRITERIA AND INSTRUCTIONS FOR PREPARATION OF SITE VISIT REPORTS

Introduction

The NCI is committed to the conduct of impartial, quality peer review of the Intramural Research Program (IRP) and to the maintenance of an objective review process. The Institute Review Office (IRO), which is organizationally independent from the NCI's Center for Cancer Research (CCR) and the Division of Cancer Epidemiology and Genetics (DCEG), is responsible for managing the peer review of the NCI IRP.

DCEG conducts population and family-based research to discover the genetic and environmental determinants of cancer as well as new approaches to cancer prevention through its programs in cancer epidemiology, genetics, statistics, and related areas. An emphasis is placed on collaborative interdisciplinary approaches that apply genomic and other emerging technologies to epidemiologic studies. Major areas of etiologic investigation include nutritional factors, environmental and occupational exposures, genetic susceptibility and gene-environment interactions, pharmacoepidemiology, infectious agents, radiation exposures, and methodologic research. DCEG is uniquely able to conduct epidemiologic research projects that are high risk, that need long-term commitments of funding and scientific staff, that require a national programmatic approach, that call for a quick response to emerging public health or scientific issues, that might go unattended by groups without a national and international reach, or that require an interdisciplinary strategy fostered by the breadth of expertise and resources in the intramural research programs of NCI and NIH.

The goal of the site visit process is to provide a rigorous scientific review of the research portfolio of DCEG intramural scientists and the leadership of the Branch Chiefs. The outcome of these reviews will assist the Division and Institute Directors in evaluating the overall quality of the research program. The site visit process ensures that the NCI uses its intramural resources wisely by supporting research that has the greatest potential to make a significant contribution to science, medicine, and public health. To accomplish this goal, the NCI relies on extramural reviewers with specialized knowledge and expertise to advise and support the Institute in its mission.

Differences Between Intramural and Extramural Review. The review of intramural research programs differs from the extramural grant review process in a number of significant ways:

- Intramural reviews are both retrospective and prospective. For senior, tenured Principal Investigators (PIs), there is a greater emphasis on accomplishments, whereas more emphasis for new tenure-track PIs is placed on future plans.

- Unlike extramural scientists, intramural PIs do not submit competitive grant applications for each of their research studies. Rather, support is provided for the PI's entire research program. For DCEG PIs, the focus is on team science that complements individual efforts. Costs for specific studies and the percent of PI efforts are provided instead of individual PI budgets.

- In DCEG, new research projects are proposed as individual concepts that must be approved by the Division=s Senior Advisory Group and the Division Director, before detailed proposals are prepared and reviewed by a protocol review committee. In addition, studies that require new research and development contracts must also seek approval from the NCI Executive Committee and the Board of Scientific Counselors (BSC).

- Resource allocations across the Division are determined largely by recommendations made to the Division Director as a result of the quadrennial site visit review process, as well as strategic priorities at NCI and NIH, Congressional and Departmental mandates, emerging public heath and policy concerns, and new scientific opportunities.

- While the entire research portfolio for each PI is reviewed at the time of the site visit, each PI typically focuses on his/her most important studies in the site visit narrative and oral presentation.

- The site visit book write-up and oral presentation have both retrospective and prospective components. Descriptions of future research plans do not contain an R01-like level of detail, but rather represent a summary of specific aims.

- Unlike extramural scientists who have the option of submitting amended applications, there is no such provision for intramural PIs to have their research re-evaluated during the site visit cycle once the BSC has made its final recommendations.

Focus of the Review. As with the scientific review of extramural research, intramural research programs should be evaluated in terms of the significance of the questions being asked, the impact on the field, the ability of the PI and the Branch to conduct important cutting-edge research that complements rather than duplicates work in the extramural research program, and the appropriateness and innovation of the approaches employed. In addition, the PI=s overall accomplishments in the field and qualifications should be assessed. It should be noted that while epidemiologic studies are usually conducted as team science, the site visit narratives and presentations allow the reviewers to identify and evaluate the individual contributions of each PI to the collaborative effort. In addition, because epidemiologic research does not lend itself to the allocation of individual PI budgets, the DCEG site visit book provides an overall Branch budget as well as the cost of individual research studies. The lead PI of each study is identified, as well as any collaborating PIs who are responsible for individual study components, thus enabling the reviewers to assess the allocation of resources to PIs across the Branch.
Review Assignments. The BSC members assigned to the site visit team will review the Branch as a

whole and the effectiveness of the Branch Chief's administrative performance, scientific leadership, stewardship of resources, and mentoring abilities. At least two scientific experts will be assigned to evaluate each PI.

Before the Site Visit. Whenever feasible, approximately one week following the mail-out of site visit materials, the Executive Secretary from the IRO may schedule a one hour teleconference with the BSC site visit co-chairs, the ad hoc reviewers, the Division Director, and immediate staff. The call allows the Division Director to orient the site visit team and answer questions prior to the preparation of site visit critiques drafted in advance of the site visit.

The members of the site visit team should prepare a typed, double-spaced draft report according to the section headers provided below for each of their review assignments, and bring a copy on a computer disk to the site visit. One week prior to the site visit, the Executive Secretary will request electronic copies of the draft reports from the individual reviewers for subsequent transmission to the site visit team. The evening before the site visit, the Division Director and immediate staff will meet with the site visit team to provide an overview and answer questions before the reviewers go into closed session.

At the Site Visit. Each PI will typically give a 20-minute presentation followed by a 25-minute question-and-answer period. This discussion period should allow PIs to fully respond to all major criticisms and questions regarding their work. In this regard, it is essential that all major criticisms and concerns are raised by the site visit team and discussed with the PI. After the Branch presentations, each PI will also meet individually in closed session (~15 minutes) with the review team. Since the site visit book write-ups and oral presentations are limited in length, this additional time provides an important opportunity for further clarification of scientific issues that may have come up earlier or were raised by the reviewers in executive session. The closed session also provides a forum for discussing other issues such as the scientific environment and administration from the PI's perspective.

Following the on-site presentations and the discussions held in executive session, each reviewer will revise the draft report based on information gained during the site visit and modify the report as needed to reflect the consensus opinion of the site visit team. It is the responsibility of the primary reviewer for an assigned component to merge the critique of the secondary reviewer and relevant portions of the panel discussion into a single report. At the final executive session (readback), the primary reviewer will read the modified report for consideration and approval by the site visit team. At the conclusion of this session, the site visit Chair will present an oral summary of the review to the Division Director.

After the Site Visit. The reports will be edited and compiled by the Executive Secretary, and the draft version will be forwarded to all site visit team members for final revisions and approval. The finalized report is forwarded to the Division Director for delivery to the Branch Chief, who then distributes relevant sections to the individual PIs. Timely delivery of the site visit report to the Branch is essential to allow sufficient time for the individual PIs and Branch Chiefs to prepare responses to the critiques, and for BSC members to prepare for the presentation and discussion of the site visit materials at the next scheduled Board meeting.

BSC Review. The BSC meets three times a year to review and make recommendations based on site visits that have occurred since the last Board meeting. The BSC members who served on the site visit team, and at least two additional readers from the Board, present the site visit report to the Board members along with the PI and Branch responses. The BSC is responsible for making final resource recommendations for the individual PIs and for the Branch as a whole. Based on their assessment, the overall recommendation will be either to continue, to expand, or to reduce the current level of resources. If expansion is recommended, the BSC may indicate whether this would apply only if additional resources were to be made available to the Branch or whether an expansion is warranted at the expense of other Branch components or investigators in times of flat or reduced budgets. If significant problems with the research portfolio are identified, the BSC may indicate whether an interim, two-year re-review of the PI=s research program is warranted or whether the research program should be closed.

BSC recommendations are a major determinant of subsequent Division, Branch, and PI resource allocations, including funding, staffing, promotion, and tenure decisions. Although implementation of the BSC recommendations is at the discretion of the Division Director, all actions taken in response to these recommendations are presented by the Director at the next scheduled BSC meeting.

Organization of the Site Visit Report

The site visit report will be in the form of narrative evaluations for the Branch and for each PI, and organized as delineated below. *Please note that the Overviews submitted in the site visit book by the Branch Chief and individual PIs will be inserted verbatim by review staff in the site visit report as an introduction to each of the sections. Reviewers need not modify nor reiterate the descriptive material in these Overviews.*

I. Site Visit Report for Individual PIs

The site visit report should evaluate the major areas within the PI=s research portfolio and provide an overall assessment of his/her scientific accomplishments. For tenure-track PIs, the site visit team should also evaluate the investigator=s progress toward achieving tenure.

A. Tenured Investigators

Scientific Evaluation

Assess the research contributions of the tenured PI, and indicate whether significant progress has been made since the last review. The assessment should address the quality of the research and research questions being asked, the impact of these contributions, and the appropriateness of the methods and approaches. Evaluate the quality, design, and management of epidemiologic, clinical, and laboratory protocols, where applicable, taking the following factors into consideration:

- **Significance/Impact on the Field:** Comment on whether the studies address significant scientific questions relevant to cancer. Has the investigator=s past research had a major

impact on the concepts that drive the field? Is there evidence of impact on clinical practice or public health?

! **Qualifications:** Evaluate the qualifications of the PI to conduct the current and/or proposed studies.

! **Approach:** Assess whether the conceptual framework, experimental design, methods, and analyses of both past and proposed research studies are/were well- developed, well-integrated, and appropriate to the aims of the project. Were/are the aims of the studies achieved/achievable? Were/are the problems or potential problems identified and adequately addressed?

! **Innovation:** Comment on the creativity and originality of the research. Does it challenge existing paradigms? Is the research developing, or does it show promise for developing novel techniques or methods? Do the studies include high-risk, high-impact projects that may be difficult to carry out in the extramural research program? Do the studies complement rather than duplicate extramural research?

! **Resource Utilization:** Examine whether there is an appropriate level of resource allocation for the current and proposed research efforts.

! **Environment:** Determine whether the PI is taking full advantage of the NCI and NIH milieu by developing productive collaborations with other PIs across the Branch, Division, Institute, the NIH, and/or the extramural community. Evaluate the PI=s role in interdisciplinary, team-based science and whether he/she is taking full advantage of the opportunities in these areas. Assess whether the PI is actively involved in NCI faculties and working groups and/or NIH-wide interest groups.

! **Future Research Plans:** Discuss the strengths and weaknesses of future research plans, including an assessment of the quality of the proposed research, and the potential scientific, clinical, and public health impact of the work. Although the likelihood of success of some high-risk studies may be difficult to judge, meritorious high-risk proposals that could be difficult to carry out in the extramural community are encouraged. Your review should be shaped by the PI=s ability to identify key research goals and to outline a suitable approach for reaching these goals.

! **Productivity:** Assess the PI=s overall level of research productivity, taking into account the time devoted to administrative or service responsibilities.

! **Training/Mentoring:** Address whether the PI is training and mentoring junior members in his/her research program, and comment on the quality and success of these efforts.

Rating Criteria for Tenured Investigators

As outlined below, rating criteria should be used to indicate the level of scientific enthusiasm for the major areas within the PI=s research portfolio as well as to assign an overall assessment of his/her scientific accomplishments. The suggested descriptors include Outstanding, Excellent, Good, Borderline, and Not Competitive. Also included are examples to distinguish among the various rating criteria. These examples are optional, and may be used or not at the reviewers= discretion when determining the level of scientific enthusiasm. If, in the course of the review, significant problems with the research portfolio are identified, indicate whether there should be an interim, two-year re-review of the PI=s research program.

Outstanding:

- Studies are world class, of exceptional quality, highly innovative and creative, and characterized by new ideas, approaches, discoveries, and paradigms that open lines of further inquiry.
- Studies have an important scientific, clinical, and/or public health impact.
- There is clear evidence of distinct intellectual leadership in collaborative research efforts.
- Several publications since the last site visit are in high-impact journals, including leading specialty journals.
- There is evidence of national/international recognition and leadership in the field, including invited lectures and memberships on editorial boards.
- Significant honors and awards have been bestowed or there has been election to scientific societies.
- Success in training and mentoring junior colleagues at all levels is evident by their professional progress, competitive funding, and/or publications.

Excellent:

- Studies are original and well designed, with a clear scientific, clinical, and/or public health impact.
- Demonstration of intellectual contributions to collaborative research efforts.
- The number and quality of publications since the last site visit demonstrates sustained productivity, with papers published in major journals, including appropriate specialty journals.
- Evidence of national/international recognition and leadership, including invited lectures and membership on editorial boards.
- Success in training and mentoring junior colleagues.

Good:

- Well-designed studies, some of which are considered to be innovative.
- Reasonable contributions to the research team=s efforts.
- A number of publications since the last site visit.
- Demonstrated recognition at the national level.
- Some evidence of successful mentoring of junior colleagues.

Borderline:

- $ Some well-designed studies, but others appear to be poorly conceived.
- $ Limited contributions to collaborative research efforts.
- $ Moderate-to-little productivity, with relatively few first, second, or last authorships since the last site visit.
- $ Limited evidence of a national reputation.
- $ Limited success in mentoring junior colleagues.

Not Competitive:

- $ Studies are consistently of poor design and not well thought out.
- $ No clear contribution to the collaborative research efforts and no demonstration of collegial working relationships with scientific peers.
- $ Few or no publications since the last site visit.
- $ Little evidence of a national reputation, with few or no invited lectures.
- $ No success in mentoring junior colleagues.

B. Tenure-Track Investigators

Scientific Evaluation

The scientific evaluation of tenure-track PIs is similar to that for tenured PIs, except as noted. The assessment should address the major areas within the PI=s research portfolio, with special attention to the quality of the research and the research questions being asked, the impact of these contributions, and the appropriateness of the methods and approaches. Greater emphasis should be placed on evaluating the tenure-track PI=s proposed future plans than would be the case when reviewing the portfolio of a more established tenured investigator.

Rating Criteria for Tenure-Track Investigators

Site visitors are strongly encouraged to provide descriptive assessments of tenure-track investigators. The use of the tenured PI rating criteria of Outstanding, Excellent, Good, Borderline, and Not Competitive is optional, and if employed, should only be assigned in a manner that is appropriate for the tenure-track PI=s level of career development. Therefore, a tenure-track PI could be ranked as Outstanding or Excellent based on their accomplishments to date, despite not yet having achieved the level of international recognition and scientific leadership that would be expected of a tenured PI.

Progress on Tenure Track

The site visit team should review the source and quality of the mentoring for each tenure-track PI. They should evaluate whether the PI=s accomplishments merit continuation on tenure track, and should also comment on the PI=s progress toward meeting the NIH criteria for tenure. These include: quality and creativity of research; originality and impact of scientific contributions to a specific field and to biomedical research more generally; scientific independence and intellectual contributions to collaborative research projects; productivity relative to resources; national and international recognition and leadership;

mentorship abilities and activities; ethical standards and integrity in directing and conducting research; and NIH citizenship and collegiality.

As part of this assessment, the site visit team should indicate whether they believe that the PI=s research trajectory is consistent with the expectation that he/she will be proposed for tenure when appropriate. For investigators with sufficiently developed programs, site visitors may indicate whether the investigator is ready to be considered for tenure, or is likely to be ready after an additional 1-2 years.

The site visit team may also suggest specific areas where improvements in the tenure-track PI=s performance are warranted or note if there is a need for an interim, two-year re-review of the PI=s research program. In addition, if the scientific evaluation indicates that it is unlikely that the PI will ever reach the level of accomplishment necessary to achieve tenure, the site visit team can recommend closure of the program and removal of the PI from the tenure track.

II. Site Visit Report for the Branch

The Branch is comparable to a university Department. The Branch Chief serves in an administrative role similar to that of Department Chair, and the PIs are independent investigators relative to tenured or tenure-track appointments within a Department. PIs within successful Branches share common scientific interests and benefit from the intellectual synergy created as the result of their association in that organizational unit. The site visit report for the Branch should include an evaluation of the quality and impact of the overall research program and an assessment of the Branch Chief's effectiveness as an administrator, steward of resources, scientific leader, and mentor.

A. Scientific Evaluation of the Overall Branch Program

- Provide an evaluation of the overall success and quality of the Branch research program, covering characteristics such as the size and focus of the program, integration of and synergy between the specific research efforts, productivity resulting from collaborations between PIs within the Branch and across the Division and Institute, the appropriateness of Branch contract and CRADA arrangements, if applicable, and the PIs= usage of these support mechanisms. The progress of individual PIs need not be addressed here.

- Assess plans for major programmatic changes, e.g., recruitment of new PIs or changes in scope or direction of the research program, taking into consideration whether the proposed changes will or will not strengthen or complement existing research areas, identify and exploit new research opportunities, or otherwise add value to the programmatic mission of the Branch, Division, and Institute.

B. Scientific and Administrative Evaluation of the Branch Chief

- Evaluate the scientific leadership of the Branch Chief as well as his/her ability to provide a stimulating scientific environment for the Branch members, and to identify promising new research opportunities. Discuss whether there is evidence of strategic planning or priority setting to achieve long-range scientific goals.

- Assess the mentoring skills of the Branch Chief. Discuss whether the mentoring of junior investigators, including tenure-track PIs and fellows, follows a well-structured approach, and review how well the Chief has supported their career development.

- Evaluate the Branch Chief=s management skills, taking into consideration whether the Branch functions as an efficient and productive unit. If new staff were sought since the last review, how effective was the Branch Chief in recruitment? If there are collaborative research efforts with outside investigators, or if technology transfer or translational activities have been established, do these efforts run smoothly and efficiently?

- Assess stewardship of resources across the Branch. Are resources allocated equitably and appropriately to PIs based on the scientific merit of the proposals? Does the allocation of resources by the Branch Chief encourage scientific independence and productivity of the PIs while fostering collaborative arrangements?

- Assess whether the key components of the Branch=s operation are productively integrated into the Branch as a whole and into related programs of the Division and Institute.

- Evaluate the utilization of core facilities and other service/support contracts based on the need and quality of their service. Address the number of researchers served by these resources; whether state-of-the-art procedures are used; the appropriateness and effectiveness of facility/contract support staff; quality control measures developed by Branch staff; evaluation of cost effectiveness; resource management and accountability; and whether significant scientific contributions are commensurate with the availability and use of these resources.