

PREPARATION OF THE CENTER FOR CANCER RESEARCH (CCR) SITE VISIT REPORT

- CCR Goals and Mission
- Focus of the Review
- Differences Between Intramural and Extramural Review
- Detailed Chronology and Goals for the Site Visit Review Process
- Instructions for Preparation of the Site Visit Report
 - Review for individual Principal Investigators
 - Review for Tenure Track Investigators
 - Review for Lab/Branch
- Appendix 1: Timeline of Site Visit and BSC Activities
- Appendix 2: Summary of Descriptors for Tenured, Senior Investigators

CCR Goals and Mission

The CCR was created with the goal of building a cancer research center that pioneers novel approaches to translational and clinical research through its strengths in basic research. A strong basic science foundation, coupled closely with innovative technology development and outstanding clinical investigators within the NIH Clinical Research Center, afford the CCR a unique opportunity to achieve this goal, and to provide outstanding training in basic, translational, and clinical research. The mission of the CCR is to reduce the burden of cancer through exploration, scientific discovery, and rapid translation of basic research to cancer prevention, diagnosis, and treatment.

High quality and high-risk basic science form the foundation for CCR's research portfolio. Innovative, concept-based clinical research trials that are applicable to the prevention or treatment of many cancer types are a focus of intramural clinical studies. The CCR is dedicated to the recruitment and free medical care of patients from across the U.S. enrolled in innovative clinical trials. Efforts are made to provide care for minorities and underserved populations. Areas of ongoing concept-based studies include, but are not limited to: cancer prevention, cancer genetics, molecular profiling, early detection, molecular targets, immunotherapy, adoptive cell transfer therapy, radiation biology, innovative combination treatment regimens, and drug resistance.

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 to conduct innovative, cutting-edge research, and the appropriateness and innovativeness of the approach(es) employed. PIs who have leveraged the distinctive resources and environment of the CCR, NCI and NIH are highly valued. Evaluating the scientific quality of the various components of the CCR via the quadrennial site visit process represents a critical determinant of their viability, and ultimately affects their resource allocation.

Review expectations include evidence of continued progress in making significant scientific contributions since the last review, current work being at the forefront of the PI's research field, and future plans demonstrating ability to develop novel research proposals. Success can be judged through both independent scientific achievement and/or distinctive, high-quality contributions to interdisciplinary, team-oriented science where the contributions have been instrumental for the success of the project. Translation of basic discoveries toward application for the diagnosis, prevention, and treatment of cancer and cancer-associated disease is highly valued.

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. Both research accomplishments and future plans are evaluated. For junior-level PIs, greater emphasis may be given to future plans. While the site visit book write-up has 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, their rationale, and potential significance.
- CCR PIs have the freedom to pursue high-risk studies and embrace exciting new research opportunities in basic and translational research that take advantage of the PI's particular strengths without review/approval. It is not necessary for a PI to follow the course proposed at the previous site visit, although the PI must be able to defend his/her decision to follow an alternative line(s) of investigation that represented an even greater scientific opportunity.
- Intramural PIs do not submit competitive grant applications for each of their research projects. Rather, support is provided for the PI's entire research program. In the intramural review, the site visit and BSC process do not lead to the submission of amended applications by the PI, which means that the BSC recommendations are final. Although an intramural PI's entire research portfolio is under review, each PI typically focuses on his/her most important projects.
- CCR PIs are encouraged to collaborate with intramural and extramural colleagues, and participate in scientifically meritorious multidisciplinary and interdisciplinary projects. Appropriate scientific credit should be given for distinct collaborative contributions for which leadership, significant scientific contributions, or training and mentoring are evident even if they do not lead to first or last authorship in publications.

Detailed Chronology and Goals for the Site Visit Review Process

Context of the Site Visit/BSC Process. The CCR uses a two-phase process of review (see Appendix 1). The first phase, conducted by the site visit team, is to provide a thorough scientific critique in the context of the criteria discussed under “Differences Between Intramural and Extramural Review (p. 3), and under “Instructions for Preparation of the Site Visit Report” (see below). The second phase of the review is conducted by the BSC, where the scientific evaluation of the PIs and the Lab/Branch is considered in the context of the overall portfolio of the CCR. It is also the responsibility of the BSC to make resource recommendations to the Center Director.

Review Assignments. The BSC members assigned as Chairpersons to the site visit team will review the Lab/Branch as a whole and the effectiveness of the Lab/Branch Chief’s administrative supervision, scientific leadership, and mentoring abilities. At least two scientific experts will be assigned to evaluate each PI.

Before the Site Visit. Reviewers should: 1) provide a preliminary evaluation of the written site visit reports provided; 2) prepare a typed, double-spaced draft of this evaluation, using the section headers below for each of their review assignments, and 3) bring an electronic copy to the site visit. One week prior to the site visit, electronic copies of individual reviewers’ draft reports will be requested by the Executive Secretary for transmission to all members of the site visit team.

At the Site Visit. The focus of this process should be a scientific evaluation and a determination of the overall quality and impact of the research program. CCR leadership will provide a pre-site visit orientation to the review team the night before the site visit and consider any questions raised by the review team. The site visit will begin with an overview of the Lab/Branch being reviewed, which is presented by the Lab/Branch chief. Following the overview, each PI will 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 concerns 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 Lab/Branch presentations, each PI will meet individually in closed session (~15 minutes) with the review team. The closed session provides a confidential forum for discussing other issues, such as scientific environment, administration, etc., from the PI’s perspective.

Following the on-site presentations and discussions in executive session, each reviewer will *revise the report based on information gained during the site visit and modify the report as needed* to reflect the consensus or majority opinion of the review team. It is the responsibility of the primary reviewer for an assigned component to merge the secondary reviewers’ critiques and relevant portions of the panel discussion into a single report. At the final closed session (readback), the primary reviewer will read the modified report for consideration and approval by the site visit team. Also at the final closed session, the site visit Chair will present an oral summary (debriefing) of the review to CCR leadership.

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 Center Director for delivery to the Lab/Branch Chief, who then distributes relevant sections to the individual PIs. Timely delivery of the site visit report to the Lab/Branch is essential, to allow sufficient time for the PIs to prepare responses to their individual critiques, and for BSC members to prepare for the review of the site visit report at the next scheduled BSC meeting, where final summary and resource recommendations are made.

BSC Review. The BSC meets three times a year to review and make final recommendations for the site visits that have occurred since the last Board meeting. The BSC members from the site visit team, and at least two additional readers from the Board, present the contents of the site visit report to the Board members, along with the Lab/Branch responses. The BSC may endorse or modify the site visit team's recommendations. The BSC recommendations often affect subsequent funding, staffing, promotion, and tenure decisions. Implementation of the BSC recommendations is at the discretion of the Center Director. All actions taken in response to these recommendations are presented at the next scheduled BSC meeting.

Instructions for Preparation of the Site Visit Report

Organization of the Site Visit Report. The site visit report will be in the form of narrative evaluations for the Lab/Branch and for each PI, organized as delineated below. *Please note that the scientific portion of the Overviews submitted in the site visit book by the Lab/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 scientific material in these Overviews.* Site visitors will be asked to verbally convey their overall impression concerning whether the Lab/Branch and the labs of the individual PI's are appropriately resourced to the chairs of the site visit team, who will prepare a written summary and bring these issues forward at the next meeting of the Board of Scientific Counselors, where final resource recommendations for labs are determined. The primary focus of the site visit review is the strength and impact of the science being reviewed.

Site Visit Review for Individual PIs. The site visit review for each PI should be divided into two sections: a) scientific evaluation; and b) summary. For tenure-track PI's, the site visit team should evaluate the investigator's progress toward tenure (see below).

Scientific Evaluation of PI. Please provide a critical assessment of the research contributions of the PI, using the following criteria:

- **Significance/Impact of the Scientific Program:** To what degree do the past and proposed studies address significant scientific questions/hypotheses? Describe the scientific, clinical, or public health impact of the PI's research on the concepts that drive the field, and the likelihood of future impact from the proposed research. What are the distinct features of the PI's past and proposed research?

Would the proposed research be difficult to perform in the extramural setting?
Are there important contributions by the PI to significant/valuable team-based projects?

- **Approach:** Evaluate whether the conceptual framework, experimental design, methods and analyses of both past and proposed research are well-conceived, well-integrated and appropriate to the aims of the project. Were/are potential pitfalls and alternative approaches identified and adequately addressed?
- **Innovation:** Research programs can be creative and innovative in several different ways. Possibilities include research that: provides a conceptual breakthrough or important new insight, proposes alternate hypotheses/explanations to commonly held opinions, poses totally new questions, represents discoveries that open further lines of inquiry, is high-risk/high-impact, develops important technical advances such as new techniques or substantial improvements, or contributes to distinctive and valuable team-oriented projects and accomplishments.
- **Collaborative and Team Science:** If the PI is involved in collaborative, multidisciplinary, and/or interdisciplinary research, what is his/her role in driving the project(s) forward? Is he/she leading a major effort within the project or making key scientific contributions to it? What accomplishments/achievements can be attributed to the PI? Was the contribution essential for the overall success of the project? To what degree did the contribution influence the overall outcome/direction of the project? Was the contribution original rather than a reproduction of the work of others (e.g., did the PI develop software with novel, original features that will be used by others in the field, or did the PI merely modify existing software to make it compatible with the workflow of the project)? For PIs whose research is mainly collaborative, how is the contribution of the individual PI regarded in the PI's field of research?
- **Achievement and Use of Current Resources:** Considering the investigator's other responsibilities (e.g., service, or administrative roles) and his/her resources, how would you rate his/her overall investigator-initiated and programmatic research productivity? Quantity should not necessarily be favored over quality. Has the PI utilized the available resources efficiently and effectively?
- **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/or 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.

- **Training/Mentoring:** Comment on the quality of training and mentoring of fellows and students in the PI's research program. Are there frequent meetings to discuss research projects and to present seminars, and are there opportunities to present research to outside groups in poster sessions or platform presentations? Are there trainee abstracts/publications? Are past trainees appropriately employed (where, and what positions do they currently hold)?
- **Qualifications:** Evaluate the qualifications of the PI. Comment on whether the PI has the qualifications and expertise or collaborators necessary to carry out the proposed work. Comment on whether the PI is considered to be a leader in his/her field.

Summary Evaluation. Please write a scientific evaluation summary and provide evidence for outstanding or excellent achievements when appropriate. If the research being performed is integral to the broader impact of a program, its evaluation should be elevated even if the approach is not considered innovative. If there are serious concerns about a PI's program that the team determines could be remedied by the PI, a recommendation can be made for a re-evaluation of the PI's program in two years. If the team determines that there are serious concerns that could not be remedied by a two-year review, this should also be noted in the summary. Please provide a **descriptor** for the senior PI's research program from among the following: **Outstanding, Excellent, Good, Borderline, Not Competitive** (see Appendix 2 for examples).

Tenure-Track Investigators

Reviewers are asked to review a tenure-track investigator for the quality of his/her science (based on the criteria listed above) and also state whether his/her research merits **continuation on tenure track**. For **Tenure Track Investigators**, the site visit team should comment on his/her ability to mentor, to seek and receive mentoring, and on how the PI is progressing toward achieving the NIH criteria for tenure, which include:

- High quality, originality and impact of scientific contributions to a specific field and biomedical research more generally
- Independence
- A key intellectual role for those involved in team science.
- Productivity relative to resources
- National and international recognition and leadership
- Mentorship abilities and activities
- High ethical standards and integrity in directing and conducting research
- NIH citizenship and collegiality

The following descriptors should be used for recommendations for **tenure-track investigators**:

- **ON TRACK for TENURE:** Based on the quality of the science, the site visit team concludes that the PI should remain on tenure track. The team may suggest specific areas for improvement if necessary. For investigators with

sufficiently developed programs, indicate whether they should be considered for tenure now, or after an additional 1-2 years. Consideration for tenure at NIH requires a site visit and BSC review within the past two years.

- **NOT ON TRACK for TENURE:** If the site visit team identifies problems that could be addressed/corrected by the PI if given an opportunity, a recommendation for re-review after 2 years should be considered. If the site visit team concludes that it is unlikely that the PI will ever reach the level of accomplishment necessary to achieve tenure, the PI's laboratory should be recommended for closure. Possible outcomes would include: 1) closure of the program prior to completing time on the tenure clock; or 2) closure at completion of time on the tenure clock.

Overall Lab/Branch Program Evaluation

The site visit review for the Lab/Branch should contain: a) an evaluation of the quality of the overall research program within the Lab/Branch, including the quality of collaborations within and outside the Lab/Branch; and b) an assessment of the Lab/Branch Chief's effectiveness as a scientific leader, and mentor (especially for tenure track PI's) and administrator. The progress of individual PIs need not be addressed here.

- **Overall Scientific Evaluation of the Laboratory/Branch**

Effective Labs/Branches may, or may not, have a thematic focus. However, the various research groups should benefit intellectually from their association with the organizational unit. The Lab/Branch environment should encourage and support each research group to achieve its maximum scientific potential.

In the site visit report, indicate your overall level of enthusiasm for the Lab/Branch program, covering characteristics such as the size and focus of the program, integration of and synergy among the research efforts, productivity resulting from the PIs' collaborations, and role in multidisciplinary and interdisciplinary research efforts. If applicable, consider the appropriateness of Lab/Branch contract and CRADA arrangements, and the PIs' use of these funding mechanisms.

For Labs/Branches that have a clinical component, provide an overall assessment of clinical units/services. Your review should consider the overall need for the unit/service, volume and quality of the service and a general assessment of the qualifications of the clinical investigators. Also consider the specific clinical research protocols/portfolio as to scientific merit, protocol design, productivity, and management.

- **Administrative Evaluation of the Lab/Branch Chief**

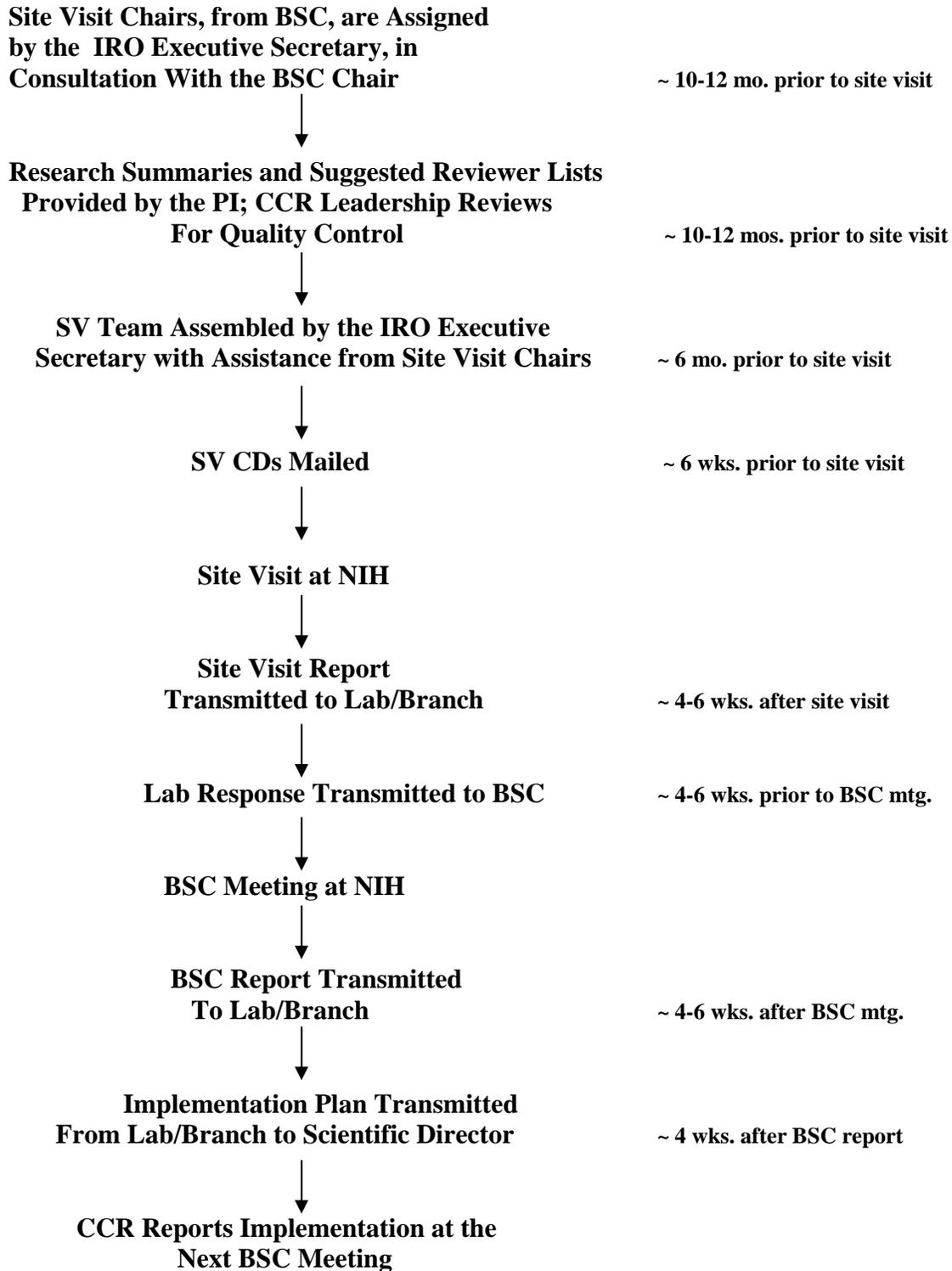
Assess the Lab/Branch Chief's management skills, taking into consideration whether the Lab/Branch runs as an efficient unit. If new staff were sought since the last review, did the Lab/Branch Chief do an effective job in recruitment?

Assess whether there is fair and appropriate access to shared Lab/Branch resources and whether maximum scientific achievement is encouraged by the Lab/Branch Chief. Evaluate intra-laboratory core facilities and contract services by assessing the quality of the service provided and need for the service. Address the number of researchers served, whether state-of-the-art procedures are used, appropriateness and effectiveness of facility support staff, cost-effectiveness, resource management and accounting, and whether significant scientific contributions have been fostered by the use of this service.

Evaluate the scientific leadership of the Lab/Branch Chief as well as his/her ability to provide a stimulating scientific environment for the Lab/Branch members. If there are Lab/Branch-wide initiatives, this assessment should include an evaluation of the Lab/Branch Chief's vision regarding future plans, especially plans to move into new research areas or discontinue others.

Assess the mentoring skills of the Lab/Branch Chief. If the Lab/Branch has tenure-track PIs, junior staff in non-tenure-track positions, or senior staff who have changed directions, review how well the Chief has supported their development.

Timeline of Site Visit and BSC Activities



Summary of Descriptors for Tenured, Senior Investigators

The following rating descriptors should be used to indicate the level of scientific enthusiasm for each area of the Senior Investigator's research portfolios as well as to assign an overall assessment of his/her scientific accomplishments. The various entries for each descriptor are intended to serve only as potential examples. If significant problems with the research portfolio are identified, indicate whether an interim, two-year re-review of the PI's research program is warranted.

- **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 independent, collaborative, and/or team research efforts.
 - Many publications are in high-impact journals, including appropriate specialty journals.
 - There is evidence of national/international recognition and leadership in the field, including invited lectures and memberships on editorial boards, participation, and leadership roles in community-wide research efforts.
 - 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 independent, collaborative, and/or team research efforts.
 - The number of publications since the last site visit demonstrates sustained productivity, with papers published in high-impact and/or appropriate specialty journals.
 - Evidence of national/international recognition and leadership, including invited lectures, membership on editorial boards, and community-wide research efforts.
 - Success in training and mentoring junior colleagues.

- **Good:**
 - Well-designed individual, collaborative, and/or team research, some of which are considered to be innovative.
 - A number of publications since the last site visit.
 - Demonstrated recognition at the national level, participation in community-wide research efforts.
 - Some evidence of successful mentoring of junior colleagues.

- **Borderline:**
 - Some well-designed studies, but others appear to be poorly conceived.
 - Limited independent achievements and/or contributions to collaborative and/or team 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, or community-wide participation.
 - Limited success in mentoring junior colleagues.

- **Not Competitive:**
 - Studies are consistently of poor design and not well thought out.
 - No clear independent, collaborative, and/or team-oriented contributions.
 - Few or no publications since the last site visit.
 - Little evidence of a national reputation, with few or no invited lectures, no participation in community-wide efforts.
 - No success in mentoring junior colleagues.