

### **REVISED**

# **Guidelines for Scientific Review by the NIEHS DIR Board of Scientific Counselors**

### **NIEHS Division of Intramural Research**

Revised September 2021

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### A. Approximate Timeline for the BSC Review Process

#### **Initial Preparations:**

#### 1-2 Years prior to review

OSD in consultation with the Lab/Branch Chief, Scientific Director, NIEHS Director, and the BSC Chair sets the review date.

#### 1 Year prior to review

Lab/Branch Chief reviews and submits suggested *ad hoc* reviewer lists [5-6 possible reviewers per investigator], reviewed by Lab/Branch Chief for possible conflicts of interest across the entire Lab/Branch<sup>1</sup>

### 6-8 Months prior to review

Revise/update Laboratory/Branch website.

OSD informs all NIEHS DIR of the upcoming Review and requests lack of conflicting events.

#### 8 Weeks prior to review

Lab/Branch Chief submits draft of each Report to the SD with copy to Deputy SD; SD/Deputy SD request alterations or approve.

#### 6 Weeks prior to review

Lab/Branch Chief submits completed PDF files of all investigators' reports to Deputy SD for indexing and compilation of Table of Contents that accompanies the complete dossier of documents submitted to the BSC

Lab/Branch Chief informs OSD of the preferred order of presentations. OSD compiles an agenda, in consultation with the Lab/Branch Chief and the BSC Chair

#### 4 Weeks prior to review

OSD sends out completed Report PDF files to the entire BSC (permanent and *ad hoc* members) via FTP [or alternate media form if requested by the recipient].

OSD also provides these materials to the SD, NIEHS Director and NIEHS Deputy Director

OSD sends hard copy of confidential financial resource documents to BSC

BSC members prepare their initial (draft) reviews using the Review Template provided to them. Members bring these reviews to the BSC meeting.

#### 2 Weeks prior to review

OSD announces the upcoming review in an NIEHS all-hands email.

#### 1 Week prior to review

OSD sends the Prior BSC Reviews of each investigator and of the "Overall Lab or Branch" review to the BSC for their consideration.

<sup>&</sup>lt;sup>1</sup> See Appendices 1 and 2 for the selection criteria for recommendation of *ad hoc* reviewers and the Conflict of Interest statement we ask all BSC members to sign. Suggestions for *ad hoc* reviewers must take these requirements into account.

#### The BSC Visit

#### **Previous Friday afternoon**

Posters are mounted for display and will remain throughout the BSC review.

#### Sunday

**Closed evening session** [BSC, NIEHS Director, Laboratory/Branch Chief and SD attending].<sup>2</sup>

#### **Monday**

**Open session** [BSC, SD, Deputy SD, NIEHS Director, NIEHS Deputy Director, entire Lab/Branch under review attending]. NOTE: This session is open to all NIEHS personnel as well the general public.

#### **Tuesday**

**Open session**, if required to complete the number of investigators being reviewed. [BSC, SD, NIEHS Director, NIEHS Deputy Director, entire Lab/Branch under review attending]. This session is open to all NIEHS personnel as well the general public.

**Closed executive session** at which the BSC will complete the following steps for each investigator who was reviewed

- 1. Complete and collect electronic copies of all panel members' review templates
- 2. Carry out final discussion and arrive at a consensus opinion for each investigator.
- 3. Create a brief "Executive Summary" narrative for the final review Document.
- 4. Following recommendations of *ad hoc* review experts, the Permanent Members of the BSC will each provide their own anonymous numerical score. The Chair will review and average the scores, eliminating any that are more than 2 standard deviations from the mean.
- 5. The Chair will announce the "descriptor" into which that numerical score falls. The Chair will also review the Executive Summary text, to ensure that the comments are consistent with the assigned score.
- 6. The BSC completes all written and scoring responsibilities prior to the debriefing.

**Debriefing** of the SD, Deputy SD, and NIEHS Director<sup>3</sup> by the BSC. Verbal comments, score and descriptor are presented for each Investigator and Core Facility under review.

<sup>&</sup>lt;sup>2</sup> The closed session that initiates the site visit typically begins at 7 PM Sunday evening. The Chief will attend to present only his/her response to the prior BSC review, and sensitive private matters such as personnel or strategic issues.

<sup>&</sup>lt;sup>3</sup> The Lab/Branch Chief is not invited to the debriefing. However, the SD and Deputy SD will meet with the Chief to deliver an informal summary of the BSC comments and unofficial scores. The "official" comments and scores are those that appear in the written critique.

#### **Activities Following the BSC Visit**

#### 1 Week after review

SD transmits the written critique verbatim to the Lab/Branch Chief, who promptly delivers the reviews privately to each investigator and reviews the contents in a private discussion.

#### 4 Weeks after review

The Principal Investigator, in consultation with the Lab/Branch Chief, drafts written point-by-point responses to the BSC review.

Note: The SD expects to see the official response within this time frame.

#### 6 Weeks after review

The SD and Lab/Branch Chief will meet to review the responses and agree upon the language of the SD Response to the BSC.

The SD will transmit a copy of the SD Response to the Chair of the BSC, NIEHS Director and also to the DDIR.

During the entire review process, there may not be any contact between NIEHS scientists under review and any actual or potential BSC regular or *ad hoc* members. This prohibition shall remain in force until the BSC has received the Scientific Director's response to the BSC review.

### **B. General Rules for Reports**

#### Formatting:

- 1. All report materials shall be prepared using Arial 11-point font.
- 2. All text shall be in black ink, except for figures and tables where color-coding is needed.
- 3. All text paragraphs are to be "full justified."
- 4. Margins shall be 1 inch all around.
- 5. Headings shall be typed in Bold Font, as is done in this Guide
- 6. Major headings shall be left-aligned to the left margin as is done in this Guide
- 7. Other outlining details are at the discretion of the author, but must be consistent throughout the entire document

#### **Quality Control:**

Each person providing a Report to the BSC is responsible for proof-reading and correcting spelling, punctuation and grammar mistakes prior to submission to the SD. It is advisable that all persons submitting reports agree among themselves to share their Reports and mutually edit and critique the documents. Figures and illustrations must be legible, and an explanatory caption must be present that defines the data being shown. OSD will not correct typographical or other preparation errors.

Reviewers are less than pleased when they detect a sloppy presentation; they ascribe these errors to lack of concern, which works to antagonize them as they consider your work.

Strive for uniformity; consider placing the highest-priority Project first, and those receiving less support or percent effort later in the report. If projects are being discontinued, state this fact—and indicate whether the work was completed, given over to a departing trainee, or abandoned to concentrate on other projects.

#### **Bibliography Citation Requirements and PubMed Central**

For all peer-reviewed papers published after April 7, 2008, Pub Med Central ID numbers ["PMCID"] must be included in the citations. Failure to include correct PMCID numbers shall result in removal of that article from the BSC Report.

Citation information should be included for all of the Investigator's published work, whether they appear in the bibliography, reference lists or CV:

Complete citation includes names of all authors, complete title and name of journal or book, page and volume numbers, and publication year. [Either e-pub or in-print pub date may be shown, so long as it is identified as such.] Format for presentation of references is left to the discretion of the Lab or Branch Chief. All investigators in the Review should strive to agree upon a consistent bibliographic format.

Example when PMCID is included: [variants to format are acceptable, provided that all the references in that section use the same format].

Fessler MB, Rose K, Zhang Y, Jaramillo R, Zeldin DC. Relationship between serum cholesterol and indices of erythrocytes and platelets in the US population. J Lipid Res. 2013 Nov;54[11]:3177-88. Epub 2013 Sep 2. PMID: 23999863; PMCID: PMC3793622.

Some articles will not yet have PMCID numbers. Example [PMC-compliant journal article during embargo period]: add at end of citation: "PMCID: PMC Journal - In Process"

PMCID numbers may be obtained from PMID numbers using the NCBI Converter Tool. If a paper has not been submitted to PMC, the procedures for doing so are available at: <a href="https://www.nihms.nih.gov/db/sub.cgi?page=faq">https://www.nihms.nih.gov/db/sub.cgi?page=faq</a>. Submission can occur through several mechanisms as summarized at: <a href="http://publicaccess.nih.gov/submit\_process.htm">http://publicaccess.nih.gov/submit\_process.htm</a>. Downloads of your publications from PubMed will also reveal PMC numbers for those papers already registered in PMC.

#### Preparation of an Adobe Acrobat PDF File of the Complete Report

Once the contents of the Report are complete, the preparer is to convert it into a single PDF file. Converted PowerPoint items used in the Report may be shown in either Landscape of Portrait orientations. It is imperative that any images that are present in the Report do not have margins [place holders] that exceed the 1-inch margin requirement. Misaligned images with this characteristic will not paginate correctly as PDF files.

### **Entering Bookmarks into a PDF File: [Contact OSD for assistance if necessary.]**

Bookmarks appear at the left-hand side of a PDF file. They are marked with this icon:

Detailed instructions for bookmarking the Report are found in Section C.

#### C. Outline and Contents of Reports

### Report from the Lab/Branch Chief: Overview

The BSC requires that the Lab/Branch Chief prepare an Overview of the Laboratory or Branch that contains the following:

- 1. Front Page [Illustration is optional]
- 2. Organizational chart of the DIR indicating the position of the Laboratory/Branch. [Request the most recent version of this document from the Deputy SD.]
- 3. Laboratory/Branch membership and brief introduction to their research roles that fit their membership in the organization
- 4. Significant awards, honors, and other scholarly activities of Investigators
- 5. Overview of the Laboratory/Branch's role in support of the mission of the NIEHS including Core Laboratories and Programmatic Functions
- 6. Other materials that the Lab/Branch Chief deems important for an accurate assessment by BSC.
- 7. PDF Bookmarks must be inserted that identify specific sections by name.

### **Required Outline of the Laboratory/Branch Chief Leadership Report:**

The BSC requires that the Lab/Branch Chief prepare a report describing their leadership of the Laboratory or Branch that addresses the following [**Not to exceed 5 pages**]:

- 1. Scientific Management: Narrative description of the efforts of the Lab/Branch Chief to create an environment conducive to the most creative and high-quality research and highlight relevant examples of the following:
  - Scientific Vision: The Lab/Branch Chief should promote and support innovative, independent science by members of the Lab/Branch and encourage new research directions within the Lab/Branch that advance the mission of NIEHS and support the 2018-2023 NIEHS Strategic Plan.
  - Education/Training: The Lab/Branch Chief should create and contribute to a positive training environment and the career development of the Lab/Branch staff. The Lab/Branch Chief must ensure a rigorous but nurturing environment for trainees and staff at all levels of career development. The Lab/Branch Chief should support and encourage trainee participation in the NIEHS Trainee Assembly and other programs offered through the NIEHS Office of Fellow's Career Development (OFCD) and the NIH Office of Intramural Training and Education (OITE).
  - Mentorship: The Lab/Branch Chief should mentor ALL colleagues in the Lab/Branch, advising them scientifically, enhancing career development, and sponsoring or advocating as appropriate. This mentoring primarily involves support of tenure-track investigators, support staff, Staff Scientists/Clinicians other PI's in the Lab/Branch, but can extend to trainees seeking advice.

- Recruitment: The Lab/Branch Chief should assist in recruiting exciting new science into the Lab/Branch as resources allow, demonstrating a strong commitment to diversify the research community.
- Collaborations: The Lab/Branch Chief should support and promote collaborations both within and outside the Lab/Branch that advances science and creates productive teams both within the Lab/Branch and across the NIEHS and NIH.
- For Clinical Programs: The Lab/Branch Chief should oversee and evaluate new clinical research protocols, facilitate scientific and IRB review, and assure the diversity of clinical cohorts used in human subjects' research and compliance with human subject regulations.
- Administrative Management: Narrative description of efforts of the Lab/Branch Chief to create and foster an outstanding workplace environment for scientific and administrative staff including the following as appropriate:
  - Stewardship of Resources: The Lab/Branch Chief should manage resources in an
    equitable, merit-based, and transparent manner to encourage scientific advances and
    innovation without bias or favoritism. These include, but are not limited to: personnel,
    contracts, discretionary funds, equipment, space, prioritization of unmet needs/end of
    year funding requests, travel and operating funds (unique to some Branches). The
    Lab/Branch Chief should also provide oversight and management of Cores, service
    centers and programmatic functions embedded within their Lab/Branch.
  - Communication: The Lab/Branch Chief should serve as an advisor to the Scientific Director and an active participant in DIR Council. The Lab/Branch Chief should meet regularly with the Principal Investigators, Administrative Officer (AO) and administrative team, and trainees, and communicate relevant information to members of the Lab/Branch.
  - Personnel Evaluations: The Lab/Branch Chief should fairly and accurately evaluate performance of direct reports and oversee the PMAP process for all investigators and staff and manage awards, spring increases (Title 42) and other salary increases/promotions for Laboratory/Branch personnel. This includes coordination of Lab/Branch BSC reviews in collaboration with the Office of the Scientific Director.
  - Safety, Privacy, IT Security and Technology Transfer: The Lab/Branch Chief should support a culture of laboratory safety, IT security and appropriate tech transfer practices, ensuring information is communicated and prescribed practices are followed.
  - Leadership change: The Lab/Branch chief should participate in succession planning as appropriate to promote outstanding science.
- 3. Ethical Leadership: Narrative description of how the Lab/Branch Chief functions as an ethical leader including in the following:
  - Role model: The Lab/Branch Chief should exhibit ethical and professional behavior of the highest standards, demonstrate integrity and have strong interpersonal skills.

- Diversity and Inclusiveness: The L/B Chief should make every possible effort to create
  and sustain an inclusive research environment in the L/B and to recruit a diverse pool
  of candidates for open L/B positions, including women and members of groups underrepresented in biomedical research. The L/B Chief should be proactive in all aspects
  of recruitment activities, such as supporting implicit bias awareness training, NIEHS
  IRTA Diversity Program and trans-NIH programs including the Distinguished Scholars
  Program.
- Research Integrity: The Lab/Branch Chief should foster a climate of the highest research integrity.
- Interpersonal Issues: The Lab/Branch Chief should address interpersonal issues
  including harassment (both bullying and sexual harassment and other inappropriate
  behavior) and inappropriate relationships quickly, appropriately, and effectively,
  including required reporting or intervention at the level of CIVIL and/or OITE to resolve
  disputes.
- Workplace Climate: The Lab/Branch Chief should facilitate and manage a workplace environment that is respectful of all individuals, regardless of gender orientation, religious affiliation, race, ethnicity, or national origin.

#### Required Outline of the Principal Investigator's Report:

Each Principal Investigator's own research write-up shall be organized as shown here. Investigators should submit late-stage drafts to the Lab/Branch Chief in DOCX or PDF format, as mutually agreed, to allow for comments and edits prior to completion.

Use these exact headings; they are also to be bookmarked in the submitted PDF of your Report:<sup>4</sup>

- 1. Cover Page with your name and Group Name [+Optional photo or science icon]
- 2. Current Personnel. [List of all scientists and personnel in the group, including trainees, students and special volunteers.]
- 3. Mentorship Activities
  - a. List all trainees placed since the last review. [Include all recently-departed post-doctoral and pre-doctoral trainees and their current positions.]
- 4. Collaborators
  - a. Intramural NIEHS [List of NIEHS collaborators, with Lab/Branch affiliations.]
  - b. Intramural NIH [non-NIEHS collaborators with affiliations.]
  - c. Extramural collaborators with affiliations
  - d. Core Laboratories and Programmatic Functions used
- 5. Research Progress Report [Not to exceed 25 pages, excluding Sections e and f]

[State in narrative form the research problems that are being addressed, the specific research aims/objectives, accomplishments since the last review, and future research plans.]

- a. Introduction and Environmental Health Relevance
- b. Project 1 [Not to exceed 12 pages]
  - i. Background relevant background information including the guiding hypotheses and specific aims.
  - ii. Accomplishments since last BSC review [About 2/3 of the text, can be a succinct summary for published work.]
  - iii. Future plans [About 1/3 of the text, include hypotheses to be tested, anticipated results, alternative approaches.]
- c. Project 2 [Not to exceed 12 pages]
  - Background relevant background information including the guiding hypotheses and specific aims.
  - ii. Accomplishments [About 2/3 of the text.]

<sup>&</sup>lt;sup>4</sup> Do not have headers, footers or page numbers anywhere in the PDF you submit. After your Report is approved by the SD, OSD staff will use Adobe Acrobat to install your Group Name in the Header and page-numbers in the footer at the bottom right of each page. The page numbers are to be located ½" up from the page bottom and ½" in from the page's right-hand edge, using ARIAL 12 pt. font.

- iii. Future plans [About 1/3 of the text.]
- d. Significance [State the overall impact/significance of your work to the field.]
- e. Relevance statement required ONLY if any research has been supported by a targeted NIH program, such as the Office of AIDS Research.
- f. References Cited
- 6. Evidence of Commitment to Diversity, Equity, Inclusion and Accessibility [Not to exceed 1 page]

Please indicate how you foster and promote a culture of belonging and inclusion within your lab and the IRP community. "Belonging and inclusion" here refers to the IRP's commitment to welcome, retain, and foster success in trainees and staff from a broad array of backgrounds, cultures, experiences, and perspectives. Please also describe how you foster professional/career development, promotion and well-being of trainees and staff while considering their own cultures and experiences. Please specify your plans for how you will continue to foster and promote a diverse, inclusive, and equitable research environment in your own lab and the IRP community during the next review period.

Examples may include, but are not limited to, the following:

- Service on diversity, equity and inclusion committees at NIH or elsewhere
- Engagement in training related to diversity, equity and inclusion, and social justice
- Outreach to diverse speakers
- How you mitigate bias during recruitment and candidate selection
- Efforts to ensure that workspaces and technologies are fully accessible

#### Resources:

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html https://www.edi.nih.gov/people/resources/advancing-racial-equity

7. Enhancing Reproducibility through Rigor and Transparency [Not to exceed 1 page]

Please describe the methods that you use to ensure rigor and reproducibility in the design, conduct, analysis and reporting of experimental data generated in your research group. Include a discussion of how you consider sex as a biological variable in the experiments that your research group conducts.

NIH has identified four aspects of rigorous research:

- Rigor of the Prior Research -- the research that is used to form the basis for the proposed research question.
- Scientific Rigor -- the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.
- Consideration of Relevant Biological variables (including sex) in study designs and analyses. [Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for limiting a study to one sex]
- Authentication of Key Biological and/or Chemical Resources used to conduct research

#### Resources:

https://grants.nih.gov/grants/guide/notice-files/not-od-15-103.html https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html https://grants.nih.gov/policy/reproducibility/index.htm

8. Impact of COVID-19 on research program [Not to exceed 1 page]

Please describe the impact, whether positive or detrimental, that the COVID-19 pandemic has had on various aspects of your research program. You should explicitly address the impact on workload, productivity, mentoring and professional opportunities. At your discretion you may also address personal circumstances that affected overall productivity; however, you are neither required nor expected to reveal specific details.

Examples of impacts include, but are not limited to:

- Cancellations of invited presentations, seminars, and conferences.
- Delays in publication submission and/or peer review due to the COVID-19 pandemic.
- Delays and difficulties in recruitment and/or onboarding of new trainees
- Changes in personal circumstances and family responsibilities due to the COVID-19 pandemic.
- Opportunities to address emerging health issues related to the COVID-19 pandemic.
- Opportunities to demonstrate innovation or creativity.
- Opportunities to form new collaborations.
- 9. Curriculum Vitae including complete bibliography. [List peer-reviewed primary publications separately from editorials/reviews/book chapters.]
- 10. Publications since the last review. Include all papers not previously reported that have been published or are in press. The NIH Office of Intramural Research recognizes the value of preprint servers in increasing access to publicly-funded research and allows these pre-publications to be included in BSC reports with discretion. Note that the content and supporting data will be evaluated by the BSC in order to determine the weight assigned to pre-publications. [Submitted manuscripts that are not posted on a preprint server or manuscripts in preparation that have not been accepted for publication may not be included.]
- 11. Five most significant peer-reviewed publications since the last review. [List them as complete citations including the titles; then follow with PDF's of each. Choose based upon significance to your field.]
- 12. Poster presentations [List titles and authors; then include each poster, with each part of the poster included separately as pages.]

### **Bookmarking of Principal Investigator Reports**

Enter Bookmarks using these major titles, according to this outline<sup>5</sup> with subheadings as shown in the example on the following page.

~ [	] c	over Page with PI name and Group Name
		Current Personnel
>		Mentorship Activities
>		Collaborators
>		Research Progress Report
		Evidence of Commitment to Diversity, Equity, Inclusion and Accessibility
		Enhancing Reproducibility through Rigor and Transparency
		Impact of COVID-19 on research program
		Curriculum Vitae
		Publications since the last BSC Review
>		Five Most Significant Peer-reviewed Publications since the last BSC Review
>		Poster Presentations

Please use the following outline for the sub-headings:

Cover Page with PI name and Group Name	
Current Personnel	
✓   Mentorship Activities	
List of all trainees placed since last BSC review	
✓ □ Collaborators	
NIEHS Collaborators	
Intramural NIH Collaborators (non-NIEHS) with affiliations	
Extramural Collaborators with affiliations	
Core Laboratories and Programmatic Functions used	

<sup>&</sup>lt;sup>5</sup> On a PC, highlight a line of text in the PDF, and right-click the mouse and choose "Add Bookmark." Note: Bookmarks can be moved to indent them by dragging the little icon to the right. Multi-line texts import as bookmarks WITHOUT the space at the end of each line; proofread this feature for journal and poster titles. Edit by clicking the bookmark and choosing "RENAME."

✓ ☐ Research Progress Report
Introduction and Environmental Health Relevance
✓ ☐ Project 1: Project Title
Background  Accomplishments since lost BSC review
Accomplishments since last BSC review
☐ Future Plans
✓ ☐ Project 2: Project Title
Background
Accomplishments since last BSC review
从 Future Plans
□ Significance     □    □     □     □     □     □     □     □     □     □     □     □
References Cited
Evidence of Commitment to Diversity, Equity, Inclusion and Accessibility
Enhancing Reproducibility through Rigor and Transparency
Impact of COVID-19 on research program
Curriculum Vitae
Publications since the last BSC Review
✓ □ Five Most Significant Peer-reviewed Publications since the last BSC Review
{lead author last name} et al., {publication year}, Title of paper #1 [this bookmark points to the first page of Article #1]
{lead author last name} et al., {publication year}, Title of paper #2 [this bookmark points to the first page of Article #2]
{lead author last name} et al., {publication year}, Title of paper #3 [this bookmark points to the first page of Article #3]
{lead author last name} et al., {publication year}, Title of paper #4 [this bookmark points to the first page of Article #4]
{lead author last name} et al., {publication year}, Title of paper #5 [this bookmark points to the first page of Article #5]
✓ □ Poster Presentations
Exact title of first poster [this bookmark points to first page of poster #1]
Exact title of second poster [this bookmark points to first page of poster #2]

#### Reports of Core Laboratories and Other Programmatic Functions

Each report shall be prepared by the "Programmatic Function Lead"

Use these exact headings; they are also to be bookmarked in the submitted PDF of your Report:

- 1. Cover Page with your name and Function Name [+Optional photo or science icon].
- 2. Current Personnel [List of all scientists and personnel in the group, including contractors, trainees, students and special volunteers.]
- 3. Description of Programmatic Support provided by this entity. [Do not exceed 5 pages.]
  - a. Purpose for the Institute: Describe important and crucial functions provided to NIEHS scientists and/or clinicians.
  - b. Service to the Institute: Show how this Function meets the research needs of NIEHS investigators [e.g., summarize findings of the most recent user survey if applicable].
  - c. Instrumentation and/or methods: Show how this Function provides access to state-of-the-art methods/instrumentation. This section can cover the following:
    - i. Why must these needs be supported in-house, as opposed to outsourced?
    - ii. Are the in-house needs and resources being met? If not, what is missing?
  - d. Technical/Intellectual Support: Show how the Function provides specific expertise in carrying out the function.
  - e. Functional Organization and Management: Show process for tracking, advisory committee review and oversight, reporting and delivery of work completed.
    - i. A summary of the most recent users' survey [global assessment] will be attached to the Report.
    - ii. The Report shall refer to the Function's Resource Sheet, which shows space, headcount and budget for this Function.
  - f. Training/Mentoring: Describe training or mentoring provided to NIEHS personnel/trainees who use this Function.
- 4. Researchers Utilizing this Function since the Last Review. [Show scientists and/or clinicians served.]
  - a. Intramural NIEHS [List of PI's and SS/SC's, with their titles and Lab/Branch affiliations; do <u>not</u> list trainees or biologists separately.]
  - b. Intramural NIH [non-NIEHS with affiliations].
  - c. Non-NIH, if any.
- 5. References [Repeat entries if a paper is relevant to more than one of these categories.]
  - a. Literature Cited in the Description narrative [item 3 above]
  - b. Publications arising from access to this Core Laboratory or Function.
  - c. Collaborative publications including authorship by Core Laboratory or Programmatic Function staff.

- 6. Curriculum Vitae of the Programmatic Function Lead including complete bibliography. [List peer-reviewed primary publications separately from editorials/reviews/book chapters.]
- 7. Poster presentations. A maximum of two poster presentations may be included. One poster shall present the support activities of the Function; the second [optional] poster shall be a scientific presentation by the Programmatic Function Lead on his/her own research activities. [List titles and authors; then include each poster, with each part of the poster included separately as pages.]

### **Bookmarking Core Laboratory or Programmatic Function Reports**

Enter Bookmarks using these titles, according to this outline<sup>6</sup> with subheadings as shown.

✓ 🖟 Cover Page Core/Program Lead Name
Current Personnel
∨ □ Description of Programmatic Support
Purpose for the Institute
Service to the Institute
Instrumentation and/or methods
Technical/Intellectual Support
Functional Organization and Management
☐ Training/Mentoring
$\checkmark \ \ \square$ Researchers Utilizing the Core/Program since previous review
☐ Intramural
NIH [non-NIEHS]
Non-NIH
✓ □ References
Literature Cited
Publications arising from access to this Core/Program
Curriculum Vitae of the Core Director of Programmatic Lead
>   Poster presentations

<sup>&</sup>lt;sup>6</sup> On a PC, highlight a line of text in the PDF, and right-click the mouse and choose "Add Bookmark." Note: Bookmarks can be moved to indent them by dragging the little icon to the right. Multi-line texts import as bookmarks WITHOUT the space at the end of each line; proofread this feature for journal and poster titles. Edit by clicking the bookmark and choosing "RENAME."

#### **Submission of the Completed Lab/Branch Documents to the OSD:**

The "book" to be submitted to the BSC shall consist of a set of Adobe Acrobat PDF files, one for each Principal Investigator or Core Laboratory or Programmatic Function. All PDF files shall include the Investigator's name.

All Principal Investigator Reports are to use this format for naming: Chapter [number of oral presentation order at BSC] Last Name Complete Group or Function Name.PDF

An example from the 2018 Signal Transduction Laboratory Review:



Once the SD has approved the Reports, the Lab/Branch Chief shall send all PDF's to the Deputy SD for copying and distribution. All BSC Reports, paginated and bookmarked, must be received for copying no less than a week prior to distribution. Exact adherence to the style requirements will help the Lab or Branch ensure that there are no delays.

#### **Report Distribution:**

OSD shall arrange for distribution of the review documents to all BSC Reviewers. Files are distributed via FTP file transfer. A file folder is prepared that contains the entire Lab or Branch materials as well as guides and review templates to be used by the BSC members. NIEHS investigators and senior leadership receive CD-ROM copies of the same contents. BSC reviewers may, at their option, request CD-ROM or Flashdrive copies.

The Laboratory or Branch may, at its option, arrange for duplication of hard-copy book versions for its own use. NIH policy defines the BSC books as confidential documents. Therefore, there is no requirement to distribute the materials to anybody outside of the BSC, the Lab/Branch investigators, and the NIEHS senior management. However, investigators may distribute their *own* reports to others as they see fit.

In addition to the scientific chapters, the BSC will also receive a package of hard-copy confidential materials from the OSD [after review by the Lab/Branch Chief] that includes:

- A complete Resource Report, accounting of the funds spent by the Principal Investigator or Core Laboratory/Programmatic Function since the last review, including items that do not appear under a CAN such as Core Facility usage, laboratory animal resource utilization [in-house, off-site, procurement], media, equipment purchased with the Lab discretionary budget, contract expenditures, etc.
- 2. A floor plan of NIEHS outlining specifically the rooms that the Investigator or Core Laboratory/Programmatic Function is assigned. This document also contains a complete notation of the total square feet of space.
- 3. A staffing timeline, showing the group's headcount and times in residence of each person for the past five years.

#### **D. Oral Presentations**

- 1. Only Group Leaders may give oral presentations. Staff Scientists or Staff Clinicians who do not have independent resources do not give oral presentations.
- 2. Each Group Leader being reviewed must prepare to give a 25-30-minute seminar that should be focused on their research progress since the last review and include discussions of how the research fits into the mission of the NIEHS, a broad overall picture of the Group Leader's research program and future plans.
- 3. Group Leaders with especially large resources or multiple, unrelated research projects and tenure-track investigators undergoing final pre-tenure review may request an extra 5 minutes [total 35-minute presentation]. This request is taken to the BSC and they will decide whether the request is warranted and fits into the schedule.
- 4. Each oral presentation is followed by a question and answer period. The TOTAL TIME for each investigator is 50 minutes. The BSC Chair may, at his/her option, request that the speaker stop the presentation if it is exceeding the allotted time.
- Each presentation should begin with a title slide containing the logos of the NIEHS, NIH, and DHHS, consistent with DHHS regulations. These may be downloaded from the NIEHS Junction7
- 6. Each presentation shall explain the relevance of the research to the mission of the NIEHS and how the PI's program interacts with, and contributes to, the Laboratory/Branch as a whole.
- 7. Presentations should reflect the depth and breadth of the research being done in each group. Hypotheses must be stated.
- 8. Investigators are free to present their research any way they wish; however, Lab/Branch Chiefs are to hold review sessions for all presenters, and critiques of presentations should be considered by the presenter.
- 9. At least one practice session is to be scheduled so that the SD can attend.
- 10. Pl's are advised to highlight for emphasis no more than one or two major topics that they feel are the most exciting, rather than attempting to cover all the projects in a superficial way. BSC reviewers wish to see evidence of continued advancement towards understanding of the research problem.
- 11. Presentations also need to spend some time on future plans. One-third of the written Report is supposed to be devoted to future plans; these should be mentioned in the oral presentation as appropriate and attention paid to prioritization of the various projects.
- 12. The Lab/Branch Chief being reviewed determines the order of presentations.
- 13. Please provide the BSC with copies of your slides on the day of your presentation.
  - a. Use the HANDOUTS printing function in PowerPoint; print 2-3 slides per page, preferably in color.

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<sup>&</sup>lt;sup>7</sup> SEE: https://junction.niehs.nih.gov/divisions/director/communications/graphics/logos/index.htm

#### **E. Poster Presentations**

### Presentations by members of an investigator's own research group

The primary purpose of the poster presentation at the BSC review is to allow the BSC to evaluate the Lab/Branch Staff Scientists/Staff Clinicians and trainees, and to evaluate mentoring by the Principal Investigators. Senior research technicians may also present posters at the discretion of the Principal Investigator.

- 1. There should be no more than one first-author poster per trainee/senior technician/Staff Scientist/Staff Clinician.
- 2. No poster shall be presented in which the first author is no longer at the NIEHS.
- 3. Poster presentations by trainees are optional, at the discretion of the Principal Investigator.
- 4. Recently-arrived fellows, who have a paucity of original data to present, should be discouraged from presenting.
- 5. The number of poster presenters per investigator is not limited.
- 6. All posters will be reviewed by BSC members.

#### Other posters from the Laboratory or Branch that may be presented

A Core Facility or Programmatic Function may present a maximum of two poster presentations. One poster shall present the support activities of the Function; the second [optional] poster shall be a scientific presentation by the Programmatic Function Lead on his/her own research activities.

- 1. The "support" posters should be listed along with all others in the Chief's "Overview" chapter.
- 2. It is the responsibility of the Lab/Branch Chief to ensure that Core Laboratory and other Programmatic Functions are identified using the exact title of that entity on its internal Website.
- 3. The Lab/Branch Chief may discuss the roles of these Functions in the overall mission of the Laboratory or Branch, and their service provided to the Institute as a whole.
- 4. Investigators may, at their option, refer to that poster if they wish to document its role in their research.

The OSD reserves the poster boards and arranges for them to be set up outside Conference Rooms 101ABC on the Friday afternoon prior to the BSC site visit.

The poster boards are approximately 5½ X 3½ feet.

#### **Poster Review Procedures:**

The BSC receives complete copies of the Posters at the very end of each BSC Report PDF file. In this way, the reviewers can read the poster contents prior to the poster session.

- Each poster is to be provided in the Board Report with each page containing one text section or Figure of the final poster, arranged in a logical sequence which the Presenter believes will lead the reviewer through the materials in the most understandable manner.
- 2. The first page should show the Title information and authors, the second should be the abstract, and at the end a Conclusions slide should be included.

- 3. At the time of the Poster Session each poster shall present the information as provided in the Board Report, except that a section of the final poster may have an optional space allotted for "Recent Findings Since Submission of the Poster"
- 4. Posters will be put up on the Friday afternoon preceding the BSC Review, so that NIEHS scientists may view the posters that afternoon.
- 5. While the posters are to be viewed by the BSC, non-BSC persons are not allowed to visit the posters, so as not to interfere with the review process.
- 6. Reviewers will have limited time to visit the posters. They will include their evaluations of the poster presentations into their deliberations as they deem appropriate.
- 7. The BSC will review posters presented by Staff Scientists or Staff Clinicians embedded in research groups and incorporate commentary on the qualifications and performance of the Staff Scientist/Clinician in their written critique of the Principal Investigator.

#### F. Conduct of the BSC Review Meeting

#### **Closed Meetings with the BSC**

- Sunday night: There is a closed meeting of the BSC beginning at 7:00 PM in the hotel
  that the Lab/Branch Chief, Institute Director and SD attend briefly at the start. The
  purpose of the Chief's attendance shall be limited to discussion of the response to the
  previous BSC report, to Tenure-Track Investigators who are having their final pretenure reviews, and to any highly sensitive personnel or organizational matters.
- 2. Monday and/or Tuesday as required to complete review of each investigator:
  - a. **Meetings with the trainees:** A closed BSC meeting will be held with trainees following the poster session. Only trainees attend; no OSD Staff, Group Leaders, Biologists, or Staff Scientists will be allowed.
  - b. **Meetings with Staff Scientists/Staff Clinicians:** The BSC will meet with those who presented posters: These individuals will also meet as a separate group with a subcommittee of the BSC members.
  - c. The BSC will **NOT MEET with biologists** and other technical support personnel who presented posters.
  - d. **Meetings with the Group Leaders:** The BSC will meet in closed session individually with each Group Leader for approximately 15 minutes. OSD Staff and the Laboratory Chief will not be present.
  - e. **Meeting with the Lab/Branch Chief:** A portion of this meeting will be devoted to Lab/Branch matters, prior to discussion of that investigator's personal research. The BSC may, at its option, request to meet additionally in closed session with the Lab/Branch Chief to discuss any matters arising of concern to the BSC.
  - f. The BSC meets in closed session to come to consensus statements on each investigator and to allow Permanent Members of the BSC to vote a score for each investigator. The score and descriptor must be consistent with the written comments of each reviewer. The panel is expected to reach a consensus. Unresolved differences of opinion should be very rare, and may be submitted by the committee only by preparing a separate "minority report."
  - g. **Each reviewer is to submit a complete review document** using the Review Template for each investigator to whom they were assigned. Their initial comments are to be modified appropriately based upon the oral presentation and its discussion. The reviews must be completed immediately following adjournment of the meeting.

#### 3. Final Day Activities:

- a. Debriefing to NIEHS Senior Personnel: Upon completion of the BSC's report preparation, the BSC convenes to communicate their oral assessment of each investigator and the Lab/Branch Chief to the NIEHS Director, Deputy Director, Scientific Director and the Deputy SD during a debriefing immediately prior to adjournment.
- b. The SD and Deputy SD meet privately with the Lab/Branch Chief to provide the BSC's oral assessment of each Investigator, pending receipt of the written critiques.
- c. The Chief shall meet promptly with each Investigator to convey the BSC score and SD comments, pending receipt of the final BSC Review.

#### Open meetings with the BSC:

Scientific presentation sessions by the Lab or Branch commence early on Monday morning. The sessions are chaired by the Chair of the BSC.

Attendance at the BSC meeting is open to the general public. Specific invitations are sent to:

- 1. All members, regardless of rank, of the group[s] being reviewed by the BSC
- 2. Directors of all NIEHS Divisions and the Director and Deputy Director, NIEHS
- 3. Other guests specifically invited by the BSC Chair or the Scientific Director
- 4. The agenda is posted in the Federal Register.

### Confidentiality of the meeting and its presentation materials

- 1. Written Board Reports are considered to be private, pre-decisional materials to be used in the conduct of the official business of the BSC.
- 2. No materials or notes from these presentations may be distributed in any form to anyone without the prior permission of the Scientific Director and/or the BSC Chair.
  - *Exception*: Investigators are free to distribute copies of their own presentations and reports as they see fit without seeking permission from anyone.
- 3. Oral presentations by the investigators are to be considered as public seminars. Any interested person from the public may attend.
  - a. No videotaping or other verbatim recording of the proceedings is permitted except at the discretion and direction of the BSC Chair.

#### G. NIH and NIEHS Review Criteria

### **Review of Laboratory/Branch Chiefs**

The roles of the Lab/Branch Chief are defined by the Office of Intramural Research (OIR) at NIH (<a href="https://oir.nih.gov/sourcebook/personnel/policies-recruitment-processes/roles-lab-branch-chiefs-or-equivalent">https://oir.nih.gov/sourcebook/personnel/policies-recruitment-processes/roles-lab-branch-chiefs-or-equivalent</a>). Criteria used by the BSC for evaluation of the Laboratory/Branch Chief were developed by the NIEHS Office of the Scientific Director based on OIR guidelines. The approved NIEHS Laboratory/Branch Chief Leadership Review Implementation Plan is located in Appendix 3. This formal leadership review of the Chief is in addition to the Laboratory/Branch Overview Comments written by the BSC Chair [SEE Template for Laboratory/Branch Overview Comments in Appendix 4]

### Leadership Review Criteria for Lab/Branch Chief [SEE sample Review Template in Appendix 5]

This is distinct from the review of the independent research program directed by the Lab/Branch Chief. The BSC will base their assessment on the information provided in the written Leadership Report, the Laboratory/Branch Overview report and oral presentation and interactions with the Principal Investigators, Staff Scientists and support staff during the review. The Laboratory/Branch Chief is reviewed for their performance and excellence with respect to three criteria regarding their management and leadership, using the following headings, as directed by NIH: :

- A. Scientific Management
- B. Administrative Management
- C. Ethical Leadership

### Scoring of Laboratory/Branch Chief

At the completion of the BSC Review process, the BSC compiles a specific numerical score assessment of the Laboratory/Branch Chief, thereby leading to assignment of the following descriptors:

#### **Outstanding [1.0-1.5]:**

- Clearly provides scientific vision and leadership for the Laboratory/Branch, including new research directions.
- Acts as an advisor to the Scientific Director including active participation DIR Council and service on other committees.
- Provides scientific oversight of research programs of Senior and Tenure-Track Investigators and encourage team science and interactions with other Laboratories/Branches and Divisions within NIEHS and NIH
- Advocates and negotiates for resources for Laboratory/Branch members, Cores, and Service Centers
- Committed to mentoring Deputy Laboratory/Branch Chief, Senior Investigators and Tenure-track Investigators

- Organizes and promotes Laboratory/Branch seminar series including many external speakers
- Provides leadership and accountability for the mentoring of trainees
- Provides oversight of Laboratory/Branch administrative staff and functions
- Performs required administrative duties including performance evaluations (PMAP) of investigators and staff, awards, spring increases (Title 42) and other salary increases/promotions and is responsive to data calls from ARSB and OSD
- Provides oversight/management of Cores, service centers and programmatic functions
- Advocates and foster development of technology originating from Laboratory/Branch as appropriate.
- Demonstrates a strong commitment to diversity and inclusiveness in all aspects of the role.

### Excellent [>1.5-2.0]:

- Clearly provides scientific vision and leadership to the Laboratory/Branch
- Acts as a resource/advisor to the Scientific Director including active participation DIR Council other committees
- Advocates and negotiates for resources for Laboratory/Branch members, Cores, and Service Centers
- Provides scientific oversight of research programs of Senior and Tenure-Track Investigators and encourage team science
- Committed to mentoring Deputy Laboratory/Branch Chief and Tenure-track Investigators
- Organize and promote Laboratory/Branch seminar series including some external speakers
- Provides oversight of Laboratory/Branch administrative staff and functions
- Performs required administrative duties including performance evaluations (PMAP)
  of investigators and staff, awards, spring increases (Title 42) and other salary
  increases/promotions and is responsive to data calls from ARSB and OSD
- Provides oversight/management of Cores, service centers and programmatic functions.
- Demonstrates a strong commitment to diversity and inclusiveness in some aspects of the role.

#### Average [>2.0-2.5]:

- Limited evidence of scientific vision and leadership for the Laboratory/Branch
- Participates in DIR Council and other committees
- Limited mentoring Deputy Laboratory/Branch Chief and Tenure-track Investigators
- Organizes and promotes Laboratory/Branch seminar series including few external speakers

- Provides oversight of Laboratory/Branch administrative staff and functions
- Performs required administrative duties including performance evaluations (PMAP)
  of investigators and staff, awards, spring increases (Title 42) and other salary
  increases/promotions but is not responsive to data calls from ARSB and OSD
- Provide minimal oversight/management of Cores, service centers and programmatic functions.
- Demonstrates a commitment to diversity and inclusiveness in some aspects of the role.

### **Below Average [>2.5-3.0]:**

- Limited evidence of scientific vision and leadership for the Laboratory/Branch
- Participates in DIR Council but not on other committees
- Insufficient mentoring Deputy Laboratory/Branch Chief and Tenure-track Investigators
- Laboratory/Branch seminar series includes no external speakers
- Minimal oversight of Laboratory/Branch administrative staff and functions
- Minimal attention to administrative duties including performance evaluations (PMAP) of investigators and staff, awards, spring increases (Title 42) and other salary increases/promotions and is not responsive to data calls from ARSB and OSD
- Provide minimal oversight/management of Cores, service centers and programmatic functions.
- Demonstrate limited commitment to diversity and inclusiveness.

#### **Unsatisfactory** [>3.0 or higher]:

- No scientific vision and leadership of the Laboratory/Branch
- Poor participation in DIR Council and other committees
- Lack of mentoring of Deputy Laboratory/Branch Chief and Tenure-track Investigators
- Inactive Laboratory/Branch seminar series
- Poor oversight of Laboratory/Branch administrative staff and functions
- Poor attention to administrative duties including performance evaluations (PMAP) of investigators and staff, awards, spring increases (Title 42) and other salary increases/promotions and is not responsive to data calls from ARSB and OSD
- Provide no oversight/management of Cores, service centers and programmatic functions
- Does not demonstrate a commitment to diversity and inclusiveness.

#### **Review of Principal Investigators**

Criteria to be used by the BSC for evaluation of research programs are given in the NIH BSC Orientation Guidelines.

Copies of the Review Template used by the NIEHS BSC, and the directives given to those individuals regarding NIH and NIEHS policy and procedure are sent prior to the upcoming review to each PI. Investigators are advised to read the Review Template so that you know what the BSC will be doing.

### Review Criteria for Principal Investigators [SEE sample Review Template in Appendix 7]

The Laboratory or Branch as a whole and each individual investigator are reviewed for their performance and excellence. Investigators are reviewed with respect to eight criteria regarding their own research and group activities, using the following headings, as directed by NIH:

- A. Significance
- B. Approach
- C. Innovation
- D. Environment
- E. Support
- F. Investigator training
- G. Productivity
- H. Mentoring
- I. Commitment to Diversity, Equity, Inclusion and Accessibility
- J. Rigor and Reproducibility
- K. Evaluation of embedded Staff Scientist(s) or Staff Clinician(s)
- L. Evaluation of any targeted NIH research, such as Office of AIDS Research, if this investigator has described such research and received funds from this source.

#### Scoring of Tenured Investigators

At the completion of the BSC Review process, the BSC compiles a specific numerical score assessment of the investigator, thereby leading to assignment of the following descriptors:

#### **Outstanding [1.0-1.5]:**

- 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, memberships on editorial boards, 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 [>1.5-2.0]:

- 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 BSC review 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

### Average [>2.0-2.5]:

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

#### Below Average [>2.5-3.0]:

- 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-low productivity, with relatively few first, second, or last authorships since the last BSC review
- Limited evidence of a national reputation, or community-wide participation
- Limited success in mentoring junior colleagues

#### **Unsatisfactory** [>3.0 or higher]:

- 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 BSC review
- Little evidence of a national reputation, with few or no invited lectures, no participation in community-wide efforts
- No success in mentoring junior colleagues

#### **Review of Tenure-Track Investigators**

Review of Tenure-Track Investigators should follow the tiered guidelines outlined in Appendix 8 based upon years onboard at the time of review. For Tier 3 Tenure-Track Investigators, reviewers are asked to review the quality of his/her research program using the scoring system above. Also, the BSC review addresses whether his/her research merits **continuation on tenure track**. In addition to the scientific review above, the BSC also comments specifically below on how the PI is progressing toward achieving the NIH criteria for tenure. Briefly, these criteria are:

- 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 BSC provides a narrative in their report that addresses the tenure-track investigator's suitability.

### **Recommendation by the BSC Regarding Tenure**

In addition to providing a numerical score and descriptor as for any investigator, the BSC also is to provide a specific guidance regarding the future prospects of the Tenure Track Investigator. That recommendation can be any of these three statements:

- ON TRACK FOR TENURE: Based on the quality of the science, the BSC concludes that the investigator should remain on tenure track. The BSC 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 BSC review within the past two years.
- **NOT ON TRACK FOR TENURE:** If the BSC identifies problems that could be addressed/corrected by the investigator if given an opportunity, a recommendation for re-review after 2 years should be considered. If the BSC concludes that it is unlikely that the investigator will ever reach the level of accomplishment necessary to achieve tenure, the investigator's laboratory should be recommended for closure.
- **CONSIDER FOR EARLY TENURE EVALUATION:** If upon review the BSC unanimously concludes that the investigator has already demonstrated outstanding achievements and scientific stature, and would clearly be a suitable tenure candidate at a nationally-prominent research university, they may recommend that the tenure-track investigator be considered for early evaluation.

#### **Review of Staff Clinicians**

A review process for Staff Clinicians has been implemented in addition to the standard quadrennial review by the Committee on Promotions. The review process reflects the diverse activities of Staff Clinicians and is tailored to their specific roles. A tiered process has been adopted:

- 1. Staff Clinicians who have independent resources will be reviewed by the NIEHS BSC according to the schedule established for all NIEHS Principal Investigators [at least every 4 years], including providing a written Report and making an oral presentation. Criteria for review will be identical to those used for Principal Investigators but will consider the reduced proportion of time allocated to independent research. Ad hoc peer reviewers will be present at the BSC review to evaluate the independent research carried out by the Staff Clinician. The process will be managed by the Office of the Scientific Director.
- 2. Staff Clinicians who work solely within their Supervisor's research group [e.g. they provide clinical care, teaching, or other duties in support of a Principal Investigator's program] will be evaluated by the BSC concurrent with the BSC review of their Principal Investigator. This process will be similar to the current review process of Staff Scientists in NIEHS basic research laboratories. There is no oral presentation or written report; however, the Staff Clinician will present a poster on his/her most significant activity, and will be interviewed by BSC members. The BSC report on the performance of the Staff Clinician will be included in the final report on the supervisor/Principal Investigator.
- 3. Staff Clinicians who do not have independent resources but who lead major clinical research initiatives [e.g., serve as Principal Investigator or Associate Investigator on major clinical research protocols which are deemed to be integral to the NIEHS Mission] will undergo NIEHS BSC review. This process will be coordinated by their Lab/Branch Chief in consultation with the Clinical Director and Scientific Director.
  - a. The review process will follow usual BSC procedures. A written report is required [see Report Outline pp. 12-13 for details]. An oral presentation is only required if deemed necessary and appropriate by the Scientific Director. The Staff Clinician will be evaluated based both on the quality of the research and on the programmatic function he/she provides. Ad hoc BSC members will be recruited to aid in the review process, if needed, in the opinion of the SD.
  - b. The BSC review will be at least every four years, and will be synchronized with the BSC review of the Clinical Research Branch or other Branches with thematic overlap [e.g., a Staff Clinician who oversees a major protocol on an inflammatory disease may be reviewed with the Immunity, Inflammation, and Disease Laboratory]. The process will be managed by the Office of the Scientific Director.

#### **Review of Staff Scientists**

Analogous to the review process for Staff Clinicians, Staff Scientists also will be reviewed and their performance evaluated.

- Staff Scientists who have independent resources allocated to them by the Scientific Director will be reviewed by the BSC according to the schedule established for all NIEHS Principal Investigators [at least every 4 years]. Criteria for review will be identical to those used for Principal Investigators. Both a written report and an oral presentation are required. Ad hoc peer reviewers will be present at the BSC review to evaluate the independent research carried out by the Staff Scientist. The process will be managed by the Office of the Scientific Director.
- 2. Staff Scientists who work solely within their Supervisor's research group [e.g., they carry out and guide the Group's research, and assist in training and administration of the group's various functions] will be evaluated by the BSC concurrent with the BSC review of their Principal Investigator. A Staff Scientist will present a poster on his/her most significant activity and will be interviewed by BSC members. The BSC report on the performance of the Staff Scientist will be included in the final report on the supervisor/Principal Investigator.
- 3. Staff Scientists who act as Managers of Core Laboratories and other Programmatic Functions are called "Programmatic Function Leads." Their review is distinct from those of the other Staff Scientist types. The BSC will be charged to assess the Function, and thereby the management of that entity as provided by the Programmatic Function Lead.
  - a. These Functions are evaluated every four years using a Customer Satisfaction Survey, conducted by the Office of the Scientific Director, open to all end-users of their services.
  - b. Each Programmatic Function Lead shall prepare a written Report to the BSC [see above] at the time when their Lab or Branch is reviewed. The BSC, based upon the Report and other materials provided, shall evaluate that Function according to criteria shown in Appendix 11.
  - c. After review of the BSC comments and end-user survey, the SD may at his/her discretion convene a special *ad hoc* panel of extramural experts to carry out a formal review of the Core Laboratory or Programmatic Function in question.
  - d. Scientific credentials and evaluations of Staff Scientists are carried out separately by the Committee of Promotions IV every 4 years.
- 4. Staff Scientists who lead major research initiatives [e.g., acting as Principal Investigator or Associate Investigator on major long-term population-based studies] may undergo BSC review. The Scientific Director will determine if BSC review is warranted.
  - a. The review process will follow usual BSC procedures. A written report is required [see Report Outline pp. 11-12 above for details]. An oral presentation is only required if deemed necessary and appropriate by the Scientific Director. The Staff Scientist will be evaluated based both on the quality of the research and on the programmatic function he/she provides. Ad hoc BSC members will be recruited to aid in the review process, if needed, in the opinion of the SD.
  - b. The BSC review will be at least every four years, and will be synchronized with the BSC review of the relevant Lab/Branch overseeing that Function. The process will be managed by the Office of the Scientific Director.

#### H. Response to the BSC Critiques

The process for handling the BSC written critique and response is as follows:

- 1. The written review is provided to the SD by the BSC Chair.
- 2. The SD forwards a verbatim copy of the BSC review to the Lab/Branch Chief.
- 3. The Lab/Branch Chief gives each investigator a copy only of the critique of his/her own research. [NOTE: The Chief should carry out this transmittal of the written critique in a personal meeting with the investigator, not merely by emailing the document. This consideration is especially important in any case in which the scientist will receive major negative comments.]
- 4. The Lab/Branch Chief shall draft a response to the review. The responses from each investigator are to be collated and edited by the Lab/Branch Chief. The Lab/Branch Chief also must respond directly to any review comment dealing with the Lab/Branch as a whole, its administration or to recommendations regarding their leadership and management of the Lab or Branch.
- 5. The format of each Pl's response to the BSC shall be shall be the same as the BSC Reports:
  - a. Page details:
    - i. 1-inch margins; Arial 11-point font; Black ink; full justified margins.
    - ii. Header on each page shall appear on the top left, and state: Response to BSC Reviewer Comments Full name of PI [e.g., Darryl C. Zeldin].
    - iii. Page number in lower right of each page
  - b. Response Content and Format:
    - i. Identify the source of each comment [e.g., "Reviewer 1" or "BSC Chair" if from the front-page summary.] Use BOLD, Italics, Underlined for this identifier.
    - ii. Quote and italicize the BSC reviewer's specific comment to which the response will be made.

**BSC Chair:** "Dr. X would be well-advised to consider collaborating more fully with others at NIEHS who share similar interests, but whose approaches are technologically quite different."

<u>Reviewer 2:</u> "Although Dr. X has made good progress on Project 2, work on that one is being hampered by diversion of resources to Project 3 which has not yielded many results despite efforts by several postdoc's as shown in two posters."

- iii. Enter your specific response to that question, without italics. It doesn't hurt to be solicitous, e.g. [response to Reviewer 2 above]:
  - Thank you for this comment. I agree that the progress has slowed, and I plan to stop work on Project 3 shortly, as soon as we complete one set of experiments requested by reviewers of our submitted manuscript on that work.
- 6. The Lab/Branch Chief and Investigator shall jointly agree upon the contents of the Response. The SD, as official author of the report, shall revise and amend the final document as he/she deems appropriate.

- 7. Upon final approval by the SD, the Investigator and the Chief shall sign the last page of the Response, using the PDF Fillable Form Template attached to this Guide as Appendix 12. Signatures may be applied digitally or in ink; this signature page shall be delivered to the SD as a separate PDF file, in order to be incorporated into the final Response.
- 8. The SD sends the completed Response through the NIEHS Director to the BSC Chair and to the DDIR. The DDIR will have the final authority regarding acceptance of the SD response to the BSC. A copy of the response is also provided to BSC members (permanent and *ad hoc*) who participated in the review.

#### **I. Appendices**

APPENDIX 1: SELECTION CRITERIA FOR RECOMMENDATION OF AD HOC REVIEWERS

APPENDIX 2: THE NATIONAL INSTITUTES OF HEALTH CONFLICT OF INTEREST AND CONFIDENTIALITY CERTIFICATION FOR INDIVIDUALS EVALUATING ALL NIH INTRAMURAL PROGRAMS

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#### APPENDIX 1: SELECTION CRITERIA FOR RECOMMENDATION OF AD HOC REVIEWERS

Ad hoc reviewers provide subject matter expertise to the BSC. Therefore, ad hoc reviewers should be clearly recognized as national or international experts in the field under review and shall be active, professor-level senior scientists who are recognizable even to a non-expert in the field.

A list of potential *ad hoc* reviewers should be developed by the Lab/Branch under review. The list should be circulated within the Laboratory/Branch so that any investigator can bring up potential conflicts of interest. Examples of conflict of interest situations with *ad hoc* reviewers that need to be avoided:

- A proposed ad hoc reviewer has been a co-author with the requesting scientist within the past four years. [NOTE: exceptions may be requested from the SD in the case of multi-center trials or consortia where co-authorship is incidental and no clear, direct personal collaboration has occurred between the proposed reviewer and the NIEHS scientist making the request.]
- 2. One investigator in the Lab is collaborating with an *ad hoc* reviewer suggested by another investigator.
- 3. An investigator in the Lab is a collaborator on a research grant held by a potential *ad hoc* reviewer.
- 4. An investigator has a major, irreconcilable scientific difference with an *ad hoc* reviewer suggested by another investigator in the lab, possibly precluding a fair review.
- 5. An investigator has published a paper in the past four years with an *ad hoc* reviewer suggested by another investigator in the lab.

The Lab/Branch under review should provide the Deputy SD with the names 5-6 possible *ad hoc* reviewers for each investigator 12 months in advance of the review. <sup>8</sup>

The Lab/Branch under review should also provide a list of outside scientists to be excluded as reviewers due to conflicts of interest or irreconcilable scientific disagreements.

The Chair of the BSC will select *ad hoc* reviewers with input from the SD and NIEHS Director. The selection list is not restricted to scientists recommended by the Laboratory/Branch.

The Chair of the BSC makes final assignments of primary and secondary reviewers. Specific reviewer assignments are *not* provided to the Laboratory/Branch under review or to the public.

All contact between scientists in the Lab/Branch under review and regular or *ad hoc* reviewers is prohibited until the BSC submits its written recommendations to the SD and the SD sends a response back to the BSC. All questions and comments to either regular or *ad hoc* BSC members must be communicated to the Deputy SD or to the SD for transmission to BSC members.

-

<sup>&</sup>lt;sup>8</sup> Obtain the *ad hoc* reviewer form from the Deputy SD.

# APPENDIX 2: THE NATIONAL INSTITUTES OF HEALTH CONFLICT OF INTEREST AND CONFIDENTIALITY CERTIFICATION FOR INDIVIDUALS EVALUATING ALL NIH INTRAMURAL PROGRAMS

I will recuse myself from evaluations of Laboratory/Branch/Independent Section research programs for which a real or potential conflict of interest exists. To that end, I certify that:

- To the best of my knowledge and belief, I or my spouse/domestic partner, parent, minor child, partner, or close professional associate do not have a direct or competing financial interest related to the research program, nor do I serve with an organization with such an interest:
- 2. I have not had a significant collaboration with any Laboratory/Branch/Independent Section member in the past four years;
- 3. I am not serving as a consultant for the Laboratory/Branch/Independent Section;
- 4. I have not engaged in any negotiations for prospective employment with the Laboratory/Branch/ Independent Section or am not in the process of recruiting a Laboratory/Branch/Independent Section member;
- 5. I have not been a member, mentor, or trainee in the Laboratory/Branch/Independent Section within the past eight to ten years; or
- 6. I am not a close personal friend or relative of any Laboratory/Branch/Independent Section member.

I will also avoid any actions that might give the appearance that a conflict of interest exists or could reasonably be viewed as affecting my objectivity. I understand that if I have questions, I should direct them to the Executive Secretary of the BSC. If the Executive Secretary has questions, he/she may consult with the Institute/Center Ethics Officer.

#### CERTIFICATION REGARDING CONFIDENTIALITY OF INFORMATION

I fully understand the confidential nature of the materials and review group discussions related thereto and agree [1] to destroy or return all review-related materials; [2] not to divulge or discuss these materials or the review proceedings with any individual except the Executive Secretary; and [3] refer all inquiries made of me concerning any aspect of the review proceedings to the Executive Secretary. I further understand the confidential nature of the materials distributed prior to review and the related committee and/or review discussions, and I agree to respect the confidential status of this information.

NAME [	Printed]	
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SIGNATURE:	DATE:
NIEHS LABORATORY or BRANCH REVIEWED [E	Enter complete name of Lab or Branch]
Entity's name: Click or tap here to enter text.	

#### APPENDIX 3: NIEHS DIR LAB/BRANCH CHIEF REVIEW IMPLEMENTATION PLAN

(Approved by DDIR on April 17, 2020)

#### Background

The Laboratory or Branch (Lab/Branch) is a civil and respectful community of PIs whose work synergizes to achieve more than the individual PIs and is the scientific, medical, administrative, and educational core of much of the Intramural Research Program (IRP) of the National Institutes of Health (NIH). A Lab/Branch Chief is a Senior Investigator who leads the Lab/Branch and, as such is a central figure in the fulfillment of the missions of the NIH and NIEHS.

The expectations for NIEHS Lab/Branch Chief positions are distinct from their roles as Principal Investigators (PIs) and outlined below. The importance of these positions warrants separate review of the management and leadership performance of the Lab/Branch Chiefs by the NIEHS DIR Board of Scientific Counselors (BSC).

#### **Duties and Expectations of Lab/Branch Chiefs**

Overall, the Lab/Branch Chiefs should create an environment that fosters scientific excellence and innovation, encourages collegiality and cooperation, extends leadership opportunities, promotes an inclusive environment, and provides scientific/clinical input for the Scientific Director (SD) and other NIEHS leadership.

#### **Scientific Management:**

- Scientific Vision: The Lab/Branch Chief should promote and support innovative, independent science by members of the Lab/Branch and encourage new research directions within the Lab/Branch that advance the mission of NIEHS and support the 2018-2023 NIEHS Strategic Plan.
- Education/Training: The Lab/Branch Chief should create and contribute to a positive training environment and the career development of the Lab/Branch staff. The Lab/Branch Chief must ensure a rigorous but nurturing environment for trainees and staff at all levels of career development. The Lab/Branch Chief should support and encourage trainee participation in the NIEHS Trainee Assembly and other programs offered through the NIEHS Office of Fellow's Career Development (OFCD) and the NIH Office of Intramural Training and Education (OITE).
- Mentorship: The Lab/Branch Chief should mentor ALL colleagues in the Lab/Branch, advising them scientifically, enhancing career development, and sponsoring or advocating as appropriate. This mentoring primarily involves support of tenure-track investigators, support staff, other PI's in the Lab/Branch, but can extend to trainees seeking advice.

- Recruitment: The Lab/Branch Chief should assist in recruiting exciting new science into the Lab/Branch as resources allow, demonstrating a strong commitment to diversify the research community.
- Collaborations: The Lab/Branch Chief should support and promote collaborations both within and outside the Lab/Branch that advances science and creates productive teams both within the Lab/Branch and across the NIEHS and NIH.
- For Clinical Programs: The Lab/Branch Chief should oversee and evaluate new clinical research protocols, facilitate scientific and IRB review, and assure the diversity of clinical cohorts used in human subjects' research and compliance with human subject regulations.

#### Administrative Management:

- Stewardship of Resources: The Lab/Branch Chief should manage resources in an
  equitable, merit-based, and transparent manner to encourage scientific advances and
  innovation without bias or favoritism. These include, but are not limited to: personnel,
  contracts, discretionary funds, equipment, space, prioritization of unmet needs/end of
  year funding requests, travel and operating funds (unique to some Branches). The
  Lab/Branch Chief should also provide oversight and management of Cores, service
  centers and programmatic functions embedded within their Lab/Branch.
- Communication: The Lab/Branch Chief should serve as an advisor to the Scientific
  Director and an active participant in DIR Council. The Lab/Branch Chief should meet
  regularly with the Principal Investigators, Administrative Officer (AO) and administrative
  team, and trainees, and communicate relevant information to members of the
  Lab/Branch.
- Personnel Evaluations: The Lab/Branch Chief should fairly and accurately evaluate performance of direct reports and oversee the PMAP process for all investigators and staff and manage awards, spring increases (Title 42) and other salary increases/promotions for Laboratory/Branch personnel. This includes coordination of Lab/Branch BSC reviews in collaboration with the Office of the Scientific Director.
- Safety, Privacy, IT Security and Technology Transfer: The Lab/Branch Chief should support a culture of laboratory safety, IT security and appropriate tech transfer practices, ensuring information is communicated and prescribed practices are followed.
- Leadership change: The Lab/Branch chief should participate in succession planning as appropriate to promote outstanding science.

#### Ethical Leadership:

- Role model: The Lab/Branch Chief should exhibit ethical and professional behavior of the highest standards, demonstrate integrity and have strong interpersonal skills.
- Diversity and Inclusiveness: The L/B Chief should make every possible effort to create
  and sustain an inclusive research environment in the L/B and to recruit a diverse pool of
  candidates for open L/B positions, including women and members of groups underrepresented in biomedical research. The L/B Chief should be proactive in all aspects of
  recruitment activities, such as supporting implicit bias awareness training, NIEHS IRTA
  Diversity Program and trans-NIH programs including the Distinguished Scholars
  Program.
- Research Integrity: The Lab/Branch Chief should foster a climate of the highest research integrity.
- Interpersonal Issues: The Lab/Branch Chief should address interpersonal issues including harassment (both bullying and sexual harassment and other inappropriate behavior) and inappropriate relationships quickly, appropriately, and effectively, including required reporting or intervention at the level of CIVIL and/or OITE to resolve disputes.
- Workplace Climate: The Lab/Branch Chief should facilitate and manage a workplace environment that is respectful of all individuals, regardless of gender orientation, religious affiliation, race, ethnicity, or national origin.

#### **Evaluation of the Effectiveness of Lab/Branch Chief**

Evaluations of Lab/Branch Chiefs will be conducted by the NIEHS DIR BSC during the quadrennial review of each Lab/Branch. These reviews will:

- Focus on administrative performance and scientific leadership, distinct from scientific accomplishment.
- Gauge the effectiveness of the Lab/Branch Chief in implementing all elements of the defined scientific, administrative and ethical duties and expectations outlined above by assigning and numerical score (1.0-5.0) and descriptor and providing supporting comments using a standardized review template developed in OSD (see appendix 1).
- Make explicit recommendations to the SD about renewal of the Lab/Branch Chief appointment.
- Be included in the final BSC report submitted to the DDIR.

#### **Basis for Review:**

The Lab/Branch Chief will provide two narrative reports ahead of the BSC review: 1) a Lab/Branch Overview; and 2) a 5-page Leadership Report that addresses the scientific,

administrative and ethical leadership of the Lab/Branch. In addition, the BSC will be provided additional materials from OSD relevant to their review including the results of an anonymous survey administered by OSD to all Lab/Branch staff and trainees.

- Scientific Leadership consists of creating an environment conducive to the most creative and high-quality research and would include:
  - Creating a scientific vision for the Lab/Branch consistent with the NIEHS Strategic Plan
  - Recruiting and mentoring senior and tenure-track investigators as well as trainees
  - Creating a positive training environment:
    - Organizing of Lab/Branch seminar series and journal clubs
    - Support of NTA and OFCD activities
  - Encouraging collaborative team science and interactions with other Labs, Branches and Divisions within NIEHS and NIH.
- Administrative Management consists of supporting the Office of the Scientific Director and serving as an effective bridge between the Lab/Branch and NIEHS Leadership including demonstrating:
  - Stewardship of resources
  - Effective Communication:
    - Serves as an advisor to the SD and active participant in DIR Council.
    - o Meet regularly with PIs, AO and administrative team
  - Culture of Safety, Privacy, IT Security, Tech Transfer
  - Succession Planning: supports leadership change/opportunity with input from Lab/Branch colleagues and from NIEHS leadership in the interest of and consistent with supporting the NIEHS research portfolio
- Ethical Leadership consists of serving as a role model for scientific and administrative staff by demonstrating leadership in the following:
  - Diversity and Inclusiveness
  - Workplace Climate/Strong interpersonal leadership
  - Research Integrity

The format of the Lab/Branch Chief Leadership Report (Appendix 2) and the anonymous survey (Appendix 3) are attached.

#### **Transition in Laboratory/Branch Chief**

The Lab/Branch Chief serves at the discretion of the SD and while decisions regarding continuation of the Lab/Branch Chief's administrative roles or changes to Lab/Branch structures will be informed by the reviews described above, changes consistent with the mission of the NIH or NIEHS can take place separate from the BSC review process. The following policies were enacted in DIR to facilitate these Lab/Branch Chief transitions.

- All NIEHS Labs/Branches have Deputy Chiefs to provide leadership development opportunities within the Lab/Branch.
- NIEHS has succession plans in place for all Labs/Branches.
- Recruitment for Lab/Branch Chiefs in the NIEHS DIR will proceed through an open search
  process under the oversight of the Deputy Director for Intramural Research (DDIR). When
  resources are limited, NIEHS will request special permission from DDIR to limit the search
  process to NIH or NIEHS scientific staff.

#### APPENDIX 4: TEMPLATE FOR LABORATORY/BRANCH OVERVIEW COMMENTS

BSC Review of the Select Laboratory or Branch Name: Laboratory/Branch Overview [to be completed by the BSC Chair in consultation with the Review Panel]

Date of Review: Click or tap here to enter text.

#### **Summary of Findings:**

Click or tap here to enter text.

Resources:

Click or tap here to enter text.

#### Core Service Functions [if any]:

Click or tap here to enter text.

#### **Training and Mentoring:**

Click or tap here to enter text.

#### **Interactions among Branch Members:**

Click or tap here to enter text.

#### **Seminar Program:**

Click or tap here to enter text.

#### **Critique:**

Click or tap here to enter text.

#### Recommendations:

#### APPENDIX 5: TEMPLATE FOR LABORATORY/BRANCH CHIEF LEADERSHIP REVIEW

NIEHS Laboratory/Branch Chief: Click or tap here to enter text.

#### Here are my summary comments about the Chief:

Click or tap here to enter text.

Please evaluate the following criteria by responding to the questions. You may also add additional comments as you deem appropriate to complete your evaluation of each section. You may be brief, where appropriate, but please be factual and definitive, especially when criticisms are stated.

#### A. SCIENTIFIC MANAGEMENT

1. Does the Chief have a clearly articulated scientific vision for the Laboratory/Branch consistent with the NIEHS Strategic Plan?

Click or tap here to enter text.

2. Does the Chief demonstrate a commitment to recruiting and mentoring Senior Investigators, Tenure-Track Investigators, Staff Scientists and trainees within the Lab/Branch?

Click or tap here to enter text.

3. Does the Chief foster a positive training environment through Lab/Branch seminar series/journal clubs and support of NTA and OFCD activities?

Click or tap here to enter text.

4. Does the Chief encourage collaborative team science and interactions with other Labs, Branches and Divisions within NIEHS and NIH?

Click or tap here to enter text.

5. Optional additional comments:

Click or tap here to enter text.

#### **B. ADMINISTRATIVE MANAGEMENT**

1. Please comment on the oversight of Laboratory/Branch functions by the Chief.

Click or tap here to enter text.

2. Does the Chief communicate effectively with Lab/Branch personnel and serve as an effective bridge between the Lab/Branch and Leadership?

3. Does the Chief actively participate in succession planning as appropriate?

Click or tap here to enter text.

4. Optional additional comments:

Click or tap here to enter text.

#### C. ETHICAL LEADERSHIP

1. Does the Chief facilitate a respectful, professional workplace climate based on strong interpersonal relationships and integrity?

Click or tap here to enter text.

2. Does the Chief demonstrate a strong commitment to diversity and inclusiveness?

Click or tap here to enter text.

3. Optional additional comments:

Click or tap here to enter text.

#### D. SURVEY RESULTS AND CLOSED DISCUSSION WITH STAFF

1. Please summarize your assessment of the Lab/Branch Chief based on anonymous surveys and discussions.

Click or tap here to enter text.

Select from one these choices as described in the instructions: Outstanding, 1.0-1.5, Excellent >1.5-2.0; Average >2.0-2.5; Below Average >2.5-3.0; Unsatisfactory >3.0]

ENTER your preliminary score here: Click here to enter text.

#### **Renewal Recommendation:**

Click to Select

APPENDIX 6: TEMPLATE FOR SUMMARY PAGE: PRINCIPAL INVESTIGATOR

NIEHS Investigator's Name: Click or tap here to enter text.

**BSC Final Score:** Click or tap here to enter text.

**Score Descriptor : Click to Select** 

**Narrative Executive Summary:** 

#### APPENDIX 7: TEMPLATE FOR REVIEW OF PRINCIPAL INVESTIGATORS

Name of NIEHS Investigator: Click or tap here to enter text.

Name of Reviewer<sup>9</sup>: Click here to enter text.

I served as: Click to Select

#### Here are my summary comments about this Investigator:

Click or tap here to enter text.

Please evaluate the following criteria by responding to the questions. You may also add additional comments as you deem appropriate to complete your evaluation of each section. You may be brief, where appropriate, but please be factual and definitive, especially when criticisms are stated.

#### A. SIGNIFICANCE

6. Have the investigator's studies addressed important problems? Click or tap here to enter text.

7. Are the aims of the project[s] being achieved?

Click or tap here to enter text.

8. Is scientific knowledge being advanced, and are the projects affecting the concepts or methods that drive this field?

Click or tap here to enter text.

9. Optional additional comments:

Click or tap here to enter text.

#### **B. APPROACH**

1. In general, are the approaches well-conceived?

Click or tap here to enter text.

2. When problem areas arose, were reasonable alternative tactics used?

<sup>&</sup>lt;sup>9</sup> NOTE: Your name will be deleted prior to dissemination of any of this information to the investigator. Critiques sent to the investigator are identified only as "Reviewer 1, etc." However, as with other review panels, NIH cannot guarantee confidentiality in extreme cases where disputes arise.

3. Optional additional comments:

Click or tap here to enter text.

#### **C. INNOVATION**

1. Are the aims original and innovative?

Click or tap here to enter text.

2. Do the projects challenge existing paradigms or develop new methodologies or technologies?

Click or tap here to enter text.

3. Do the studies include high-risk, high-impact projects?

Click or tap here to enter text.

4. Optional additional comments:

Click or tap here to enter text.

#### **D. ENVIRONMENT**

 Is the investigator taking advantage of the special resources and features of the NIH intramural scientific environment or employing useful collaborative arrangements? Click or tap here to enter text.

2. Optional additional comments:

Click or tap here to enter text.

#### **E. SUPPORT**

1. Is the support the investigator received appropriate?

Click or tap here to enter text.

2. 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.

Click or tap here to enter text.

3. Optional additional comments:

Click or tap here to enter text.

#### F. INVESTIGATOR TRAINING

1. Is the investigator appropriately trained and well suited to carry out the projects being pursued?

2. Is the work proposed appropriate to the experience level of the principal investigator and other researchers [if anyl?

Click or tap here to enter text.

#### 3. Optional additional comments:

Click or tap here to enter text.

#### **G. PRODUCTIVITY**

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

Click or tap here to enter text.

#### 2. Optional additional comments:

Click or tap here to enter text.

#### H. MENTORING

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

Click or tap here to enter text.

#### 2. Optional additional comments:

Click or tap here to enter text.

#### I. COMMITMENT TO DIVERSITY, EQUITY, INCLUSION AND ACCESSIBILITY

 Has the investigator demonstrated a commitment to foster and promote a diverse, inclusive, and equitable research environment their research group?

Click or tap here to enter text.

#### 2. Optional additional comments:

Click or tap here to enter text.

#### J. RIGOR AND REPRODUCIBILITY

NIH has identified four key aspects of rigorous research:

- Rigor of the Prior Research -- the research that is used to form the basis for the proposed research question.
- Scientific Rigor -- the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.
- Consideration of Relevant Biological variables (including sex) in study design and analysis.
- Authentication of Key Biological and/or Chemical Resources used to conduct research

1. Is the investigator ensuring rigor and reproducibility in the design, conduct, analysis and reporting of research studies in their group?

Click or tap here to enter text.

#### 2. Optional additional comments:

Click or tap here to enter text.

### K. EVALUATION OF STAFF SCIENTIST(S) / STAFF CLINICIAN(S) EMBEDDED IN THIS PI'S GROUP

1. For each Staff Scientist or Staff Clinician who works solely in support of the Pl's research group activities, comment upon the functions, scientific/clinical credentials and expertise of that person as evidenced from the Pl's Report, publications, oral presentation and/or the poster presented by that person

Click or tap here to enter text.

#### 2. Optional additional comments:

Click or tap here to enter text.

### L. EVALUATION OF ANY TARGETED NIH RESEARCH [SUCH AS FROM OFFICE OF AIDS RESEARCH]

- If the investigator received targeted funds and cited research carried out under that program, what is the relevance of that research to <u>high-priority research</u> needs? Click or tap here to enter text.
- 2. What is your opinion of the quality of the targeted research being carried out by this investigator?

Click or tap here to enter text.

#### 3. Optional additional comments:

Click or tap here to enter text.

Select from one these choices as described in the instructions: Outstanding, 1.0-1.5, Excellent >1.5-2.0; Average >2.0-2.5; Below Average >2.5-3.0; Unsatisfactory >3.0]

ENTER your preliminary score here: Click here to enter text.

**FOR TENURE-TRACK INVESTIGATORS:** Also make your preliminary tenure recommendation pending the presentation and BSC discussion. Select from these choices:

Click to Select

#### APPENDIX 8: REVIEW OF RECENTLY HIRED TENURE-TRACK INVESTIGATORS

BSC review is an ongoing requirement for all NIH investigators in the Intramural Research Program. Recently hired Tenure-Track Investigators (TTIs) pose a special case regarding BSC review in that they may not yet have completed assembly of their research team when their Laboratory/Branch is reviewed. The OSD and Laboratory/Branch Chief will determine an appropriate review venue (out of normal cycle with the Laboratory/Branch) if necessary, for the TTI to maintain at least one BSC review every 4 years to comply with OIR requirements.

Tier 1. TTIs who have been at NIEHS 0-1 year at the time of Laboratory/Branch review.

The NIEHS DIR proposes the following procedures for TTIs whose Laboratory/Branch is scheduled for review prior to the one-year anniversary of their official on-boarding date:

- 1. The new TTI will provide a 3- to 5-page scientific report focused on future directions for the BSC.
- 2. The new TTI will deliver a short oral presentation (generally 15 minutes or less) to the BSC.
- 3. Appropriate ad hoc reviewers will be recruited by the OSD to review the new TTI.
- 4. The TTI has the option of having their BSC review scored and indicate whether the TTI is "on track for tenure." The TTI needs to inform OSD whether they want their BSC review scored prior to submission of their written report.
- 5. The BSC will be instructed to provide constructive comments to the TTI. If the TTI requested not to have their review scored, the BSC will provide comments without providing a numerical score and without indicating whether the individual is currently "on track for tenure." Otherwise, the BSC review will be scored and indicate whether the TTI is "on track for tenure." This review should be considered as a mentoring session and an opportunity for the TTI and mentor to receive feedback on the proposed research program.
- 6. If the TTI chose not to have their BSC review scored, then the BSC's comments will not go to the NIEHS COP I, the NIH Central Tenure Committee, nor the BSC for the TTI's next BSC review.
- 7. In addition, if the BSC review is not scored, *ad hoc* reviewers recruited by OSD to review the TTI whose comments will not go to the NIEHS COP I or the NIH Central Tenure Committee may be used by the TTI as tenure recommendation letter writers.

Tier 2. TTIs who have been at NIEHS 1-2 years at the time of Laboratory/Branch review.

The NIEHS DIR proposes the following procedures for TTIs whose Laboratory/Branch is scheduled for review between the first and second-year anniversary of their official on-boarding date:

- 1. The TTI will provide a full scientific report (up to 25 pages) for the BSC following the BSC guidelines.
- 2. The TTI will deliver a standard 25- to 30-minute oral presentation to the BSC following the BSC guidelines.
- 3. Appropriate ad hoc reviewers will be recruited by the OSD to review the TTI.
- 4. The TTI has the option of having their BSC review scored and indicate whether the TTI is "on track for tenure." The TTI needs to inform OSD whether they want their BSC review scored prior to submission of their written report.

- 5. The BSC will provide a full written critique to the TTI. If the TTI requested not to have their review scored, the BSC will provide comments without providing a numerical score and without indicating whether the individual is currently "on track for tenure." Otherwise, the BSC review will be scored and indicate whether the TTI is "on track for tenure."
- 6. If the TTI chose not to have their BSC review scored, then the BSC's comments will not go to the NIEHS COP I, the NIH Central Tenure Committee, nor the BSC for the TTI's next BSC review.
- 7. In addition, if the BSC review is not scored, *ad hoc* reviewers recruited by OSD to review the TTI whose comments will not go to the NIEHS COP I or the NIH Central Tenure Committee may be used by the TTI as tenure recommendation letter writers.

Tier 3. TTIs who have been at NIEHS longer than 2 years at the time of Laboratory/Branch review.

The NIEHS DIR proposes that for TTIs whose Laboratory/Branch is scheduled for review after the second-year anniversary of their official on-boarding date that they follow the same procedures as described for Principal Investigators in the BSC guidelines. The BSC will provide a full written critique to the TTI – providing a numerical score and indicating whether the individual is currently "on track for tenure" as described in the BSC guidelines. The BSCs comments will go to the NIEHS COP I and the NIH Central Tenure Committee.

#### APPENDIX 9: TEMPLATE FOR SUMMARY PAGE: STAFF SCIENTIST WITH RESOURCES

DIR reviews Staff Scientists with independent resources in cases where they are in the laboratories of Emeritus Scientists

NIEHS Staff Scientist with Resources: Click here to enter text.

**BSC Final Recommendation:** 

Do you recommend continued support of this Staff Scientist?

Click to Select

Is the level of support consistent with research productivity and interests?

Click to Select

**Narrative Executive Summary:** 

Click here to enter text.

APPENDIX 10: TEMPLATE FOR SUMMARY PAGE: CORE LABORATORIES AND PROGRAMMATIC FUNCTIONS

NIEHS Programmatic Staff Scientist or Core Facility: Click here to enter text.

**BSC Final Recommendation:** 

Is there a continuing need for this Core Facility or Programmatic Function?

**Click to Select** 

Does this Core Facility or Programmatic Function warrant a more extensive outside review at this time?

Click to Select

**Narrative Executive Summary:** 

Click here to enter text.

### APPENDIX 11: TEMPLATE FOR REVIEW OF CORE LABORATORIES AND PROGRAMMATIC FUNCTIONS

#### A. PURPOSE FOR THE INSTITUTE

Does this Core Laboratory or Programmatic Function provide an important and crucial scientific or clinical resource to NIEHS?

#### Select response

#### **Optional Comments:**

Click or tap here to enter text.

#### B. SERVICE TO THE INSTITUTE

Does this Core Laboratory or Programmatic Function meet the research needs of NIEHS investigators?

#### **Select Response**

#### **Optional Comments:**

Click or tap here to enter text.

#### C. INSTRUMENTATION AND/OR METHODS

Does this Core Laboratory or Programmatic Function employ state-of-the-art methods and/or instrumentation?

#### **Select Response**

#### Optional Comments:

Click or tap here to enter text.

#### D. TECHNICAL SUPPORT

What is the level of scientific and/or clinical expertise displayed by this Core Laboratory or Programmatic Function?

#### **Select Response**

#### **Optional Comments:**

#### E. FUNCTIONAL ORGANIZATION AND MANAGEMENT:

#### **Select Response**

#### **Optional Comments:**

Click or tap here to enter text.

#### F. TRAINING/MENTORING

Does this Core Laboratory/Programmatic Function provide training/mentoring to NIEHS personnel/trainees?

#### **Select Response**

#### Optional Comments:

Click or tap here to enter text.

#### G. CUSTOMER SATISFACTION SURVEY

What was the general opinion of end-users in the most recent survey of this Core Laboratory/Programmatic Function?

#### **Select Response**

#### **Optional Comments:**

Click or tap here to enter text.

### H. DOES THIS CORE LABORATORY/PROGRAMMATIC FUNCTION WARRANT A MORE EXTENSIVE OUTSIDE REVIEW AT THIS TIME?

#### **Select Response**

#### **Optional Comments:**

Click or tap here to enter text.

### I. IS THERE A CONTINUING NEED FOR THIS CORE LABORATORY OR PROGRAMMATIC FUNCTION TO EXIST AT NIEHS?

#### **Select Response**

#### Optional Comments:

#### APPENDIX 12: SIGNATURES PAGE TEMPLATE FOR RESPONSE TO BSC REPORT

[Use digital signatures when possible]		
Date of the BSC Review:		
Respondent's Name:		
	Date:	
Signature		
Lab/Branch Chief's Name:		_
	Date:	
Signature		