

Roles and Review of Scientific Directors and Clinical Directors (or Equivalent)

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Background

The Scientific Directors (SDs) and Clinical Directors (CDs) are outstanding senior investigators or senior clinicians whose primary responsibilities include oversight of the NIH Institute & Center (IC) intramural scientific organization, setting overarching research priorities in partnership with the IC Director and other IC leadership, and allocating resources to achieve the research mission of the IC. The responsibilities also include the recruitment of talented and diverse individuals to conduct high-quality and ethical research that ranges from basic molecular to human subject research. The SD/CD should ensure a respectful and open organizational culture and create and sustain a research environment that is collegial, respectful, and supportive for all staff and fellows within the Intramural Research Program (IRP). Resources dedicated to this mission are substantial with approximately 12% of the total NIH budget directed to the IRP. As such, the judicious administration of these resources and the strategic recruitment of personnel who foster collaboration, respect, and transparency and understand the need for a diverse and inclusive workforce, is critical to attracting high-quality talent and maintaining the IRP's unique and distinctive environment.

Academic deans, department chairs, and division chiefs undergo regular administrative reviews at intervals that permit the demonstration of effectiveness in leading their respective programs and financial sustainability. Strategic plans and annual reviews are also commonplace. The expectation is that retention of a leadership position is contingent upon performance with clear evidence of faculty well-being, research and scholarly productivity, high-quality training and mentoring, outstanding patient care, sound fiscal administration, and a record demonstrating a commitment to diversity and inclusion. While NIH IRP leaders have different fiduciary responsibilities, it is imperative that they continuously demonstrate excellence in each of these areas that are germane to the success of the NIH.

The following general principles clarify expectations for the SD and CD positions — distinct from the roles played by these scientists as Principal Investigators (PIs). It is understood that each IRP has different needs and circumstances, and thus each IC can provide proposals with some modifications of the expectations and review process to the Deputy Director for Intramural Research (DDIR) for consideration, as long as the revisions are consistent with the principles outlined here.

Expectations for Scientific Directors and Clinical Directors

The SD/CD responsibilities focus on 1) creating an open and transparent environment in which scientific excellence and creativity are promoted; 2) fostering collegiality, collaboration, scientific synergies, and cooperation among staff; and 3) the modeling and promotion of inclusion and the development of career advancement opportunities for all staff. As the leaders of the intramural science of their institute, the SD/CD needs, above all, to have a 'judicial temperament' and to understand that their decisions and actions must always reflect fairness and civility, and the highest ethical and scientific standards. This is especially true because their actions and the standards they set will be mirrored by those throughout the institute.

Scientific Management:

- Scientific Vision: The SD/CD should promote and support innovative, independent science by members of the IC intramural faculty.
- Training and Mentoring within the IRP: The SD/CD should set policies for a standard of excellence in training and mentoring, including the teaching of scientific rigor for clinical research principles, experimentation, and data analysis; scientific ethics in the handling of data; effectively working with fellow scientists, colleagues and the public; understanding of the importance of reproducibility of scientific research and of recognizing implicit bias in one's work.
- Recruitment: The SD/CD should assist in recruiting exciting and rigorous new scientists into the IC and demonstrate a strong commitment to attracting a diverse pool of applicants, representing all demographics and differing scientific perspectives.
- Interactions with the Board of Scientific Counselors (BSC): The SD/CD should work with the BSC, which is advisory to the SD and CD, to fairly evaluate the work of the IRP Labs/Branches and all PIs within their IRP as well as the effectiveness of leadership within the IC, with the goal of improving the science and administrative management of the IRP. The BSC reports should serve as strong guidelines for future directions. The SD/CD should facilitate the process of nominating BSC members by the BSC chairs for approval by the IC Directors and the DDIR.
- For Clinical Programs: The SD/CD should collaborate with the Lab/Branch chiefs to oversee and evaluate new clinical research protocols, facilitate scientific and IRB reviews, and assure the diversity defined as equitable representation of women and racial/ethnic minorities in clinical cohorts used in human subjects' research and compliance with human subject regulations. SDs and CDs must ensure the critical review of the Cumulative Inclusion Enrollment Report for each individual study for its compliance with the NIH Policy of The Inclusion of Women and Minorities as Subjects in

Clinical Research. For studies not in compliance with the policy, SD/CDs must mandate that investigators provide a restorative plan to increase diversity. For studies repeatedly out of compliance, SDs/CDs must take direct action to ensure compliance.

Administrative Management:

- **Transparency:** It should be the overarching goal of the SD/CD to bring transparency to all processes within the IRP, including scientific direction, allocation of resources, hiring, promotions, awards and recognition, and service within leadership positions.
- **Training and Mentoring:** The SD/CD should ensure that training needs are assessed and that mentoring opportunities are provided for scientific and administrative staff.
- **Stewardship of Resources:** The SD/CD should manage resources (including personnel, contracts, equipment, space) in an equitable, merit-based, and transparent manner to encourage scientific advances and innovation without bias or favoritism.
- **Communication and Partnership:** The SD/CD should partner with and communicate regularly with each other, with the IC Director (to whom both report), with the Executive Officer, and with the administrative staff and should communicate relevant information to Lab/Branch chiefs and to the IRP as a whole.
- **Personnel Evaluations:** The SD/CD should fairly and accurately evaluate performance of direct reports and oversee the PMAP process within the IRP. They should also ensure that Branch and Lab Chiefs effectively supervise their scientific and administrative staff, articulate performance standards, provide real-time feedback and be accountable in managing the completion of tasks for the PIs and lab/branch.
- **Safety, IT Security, Records Management, and Tech Transfer:** The SD/CD should support a culture of laboratory safety, IT security, and appropriate record-keeping and technology transfer practices, ensuring written SOPs are available, information is communicated, and prescribed practices are followed.
- **Leadership Change:** The SD/CD should participate in succession planning as appropriate to promote outstanding science, outstanding administration, and outstanding leadership as well as a smooth transition for all critical positions. In this regard, the SD/CD should maintain an inclusive and transparent process to generate opportunities for scientific and administrative members of the IRP to participate in leadership, such as the development of committees to be involved in hiring, promotion, and resource decisions.

- The SD/CD should participate in NIH-wide discussions concerning policies, guidelines, rules, regulations, and legal requirements; promulgate trans-NIH requirements within their IRP; and maintain effective working relationships with the Office of Intramural Research and other central NIH offices.

Ethical Leadership:

- Role Model: The SD/CD should exhibit ethical and professional behavior of the highest standards, demonstrate integrity, and have strong interpersonal skills.
- The SD/CD should execute decisions concerning the hiring, promotion, and resource allocation of leadership positions with transparency, and communicate those decisions in such a way that the members of the IRP are aware of the process for the decision making.
- The SD/CD should provide an equitable and inclusive environment conducive to the recruitment, career development, and retention of individuals from diverse backgrounds, including women and members of groups underrepresented in biomedical research. This should be clearly demonstrated through efforts that include:
 - A demonstrated track record of recruiting a diverse pool of candidates for open positions in the intramural workforce.
 - Mentoring and training activities aimed at fostering an inclusive culture and supporting early career scientists from diverse backgrounds, including but not limited to active support for and participation in trans-NIH programs such as the Distinguished Scholars Program.
 - Having consistently equitable salary, promotion and retention policies throughout the intramural workforce at all levels.
- Research Integrity: The SD/CD should foster a climate of the highest research integrity and should be proactive and supportive of those activities that promote scientific integrity, such as the ethical training provided by the Committee on Scientific Conduct and Ethics (CSCE), and ensure that all scientific members of the IRP participate in training.
- Interpersonal Issues: The SD/CD should assure that staff at all levels in the intramural program are aware of resources available to them to address any needs related to work-life balance and any concerns related to workplace issues. The SD/CD should assure that all supervisors are held accountable for following policies and making NIH resources known. The SD/CD should collaborate with appropriate parties, including the ICEO, on any reports of interpersonal issues. The SD/CD should be fair and impartial when addressing interpersonal issues within the IRP. If those issues include harassment

(bullying, discrimination, sexual harassment, or other inappropriate behavior) and/or inappropriate relationships, the SD/CD should quickly, appropriately, and effectively require reporting or intervention at the level of Civil and/or the Office of Intramural Training and Education to resolve disputes as well as provide guidance to employees of their potential rights to utilize the EEO process by contacting EDI.

- Workplace Climate: The SD/CD should facilitate and manage a workplace environment that is respectful of all individuals, regardless of sexual orientation, gender identity, religious affiliation, race, ethnicity, or national origin. The SD/CD should demonstrate leadership and commitment by implementing IC strategies to promote a positive workplace climate and by communicating to the IRP how a respectful, diverse, and inclusive IRP contributes to the mission of the IC. The SD/CD should engage fully in these efforts by putting in place internal structures and processes that demonstrate personal commitment to these goals.

Review of Scientific Directors and Clinical Directors

The evaluation of the effectiveness of leadership is important for the vitality of any institution. This review is independent of the individual's scientific excellence. The overall scientific productivity of the IC, management of resources and budget allocations, and training activities are expected to be part of the review. However, to emphasize the importance of judicious leadership, the administrative review also must include a study of the culture of the IRP. The study should include the solicitation of input from the staff of the IRP and IC leadership (IC Director, Deputy Director, EO) about the administrative effectiveness of the leader, a comparison of the program to other ICs as well as external national benchmarks and outcome metrics where applicable, and a summary of the dimensions of diversity, inclusion and promotion of investigators and staff (including the NIH Equity Committee (NEC) reports. This self-study of the IRP should provide meaningful information that can be used to identify strengths and areas that need improvement while demonstrating an effort to either sustain an effective program or make continuous progress. The review reports should be presented by the IC Director to the IC's Advisory Council or Board, to the Deputy Director for Intramural Research, and to the NIH Director. A summary of the recommendations of the report along with proposed actions to address issues also will be provided to the investigators in the IRP.

These newly establish guidelines for the review of SDs and CDs are posted in the NIH intramural sourcebook (<https://oir.nih.gov/sourcebook/processes-reviewing-nih-intramural-science/role-review-scientific-directors-clinical-directors-or-equivalent>).

- Each SD and CD should be reviewed by an *ad hoc* external committee every six years or more frequently if the need arises. These reviews for SDs and CDs are parallel, but separate processes, and are different from a BSC review of their independent research programs, and should not be performed simultaneously. The process is initiated when the IC Director sends a letter to the Chair of the IC Advisory Council or Board, requesting

that the review of the IC SD/CD be performed. With input from the IC Director, the Council or Board is requested to establish an *ad hoc* committee, composed of at least four members, which will report to the IC's Advisory Council or Board. The committee may contain one member, who is a present or former BSC member, while the others may be drawn from the IC Advisory Council or Board (not to exceed 50% of the total membership), former IC intramural scientists, and other senior scientists and scientific administrators. The committee should consist entirely of members from outside the IRP. The membership must be approved by the DDIR and the NIH Director.

- At least 3 months before the review, the intramural staff of the IC should be polled to assess the effectiveness of the SD/CD in the areas indicated above. Tools to accomplish this include a 360-type evaluation with questions relevant to the SD or CD performance, solicitation of anonymous comments from staff of the IRP, and surveys which assure the anonymity of the responder. The results of these evaluations should be presented to the IC Director who will provide a summary to the SD/CD and the review committee. Intramural staff will also be encouraged to write directly to the chair of the review committee to share relevant comments about the SD's or CD's performance.
- The SD/CD should submit a progress report, covering the six-year period since the previous review, to the chair of the *ad hoc* committee. This report should describe short-and long-term goals and program achievements since the previous review or since assuming the position of SD/CD.
- *Ad hoc* committee review of the SD/CD should include interviews with the SD, CD, Lab/Branch Chiefs, IC scientists at all levels, the IC Director, the EO and chief administrative officer (AO), and the DDIR. Letters of reference (4-6) may be solicited as appropriate. Not more than two should be from IRP scientists or administrators.
- The Chair of the *ad hoc* review committee should submit a report to the IC Advisory Council or Board, via the IC Director, entitled "Review of the Scientific Director/Clinical Director (IC)". The report should comment on:
 - overall performance of the SD/CD as head of the IRP or the IRP's clinical program
 - scientific and programmatic accomplishments in the IRP
 - quality of training and mentoring within the IRP
 - promotion of equity, diversity, and inclusion within the IRP
 - success in assuring equitable treatment of scientists, and, where appropriate, administrative staff within the IRP
 - administrative style and skills of the SD
 - interactions with the Lab/Branch Chiefs, other PIs, the offices of the IC CD (or SD, as appropriate), the IC Director, the EO, and the DDIR

- SD/CD interactions with the BSC in general and the BSC chair in particular
- compliance of the IC's IRP with the NIH Policy on the Inclusion of Minorities and Women in Clinical Research on a study-by-study basis

Changes to Scientific Director and Clinical Director Appointments

While it is expected that the IC Director's decision regarding continuation of the SD/CD administrative roles or changes to IRP structures will be informed by the reviews described in this document, changes consistent with the mission of the NIH or the IC can take place separate from the review process described in this document. Recruitment for SDs/CDs will be public and open, with a transparent process that is communicated to the IRP before the search is initiated and transparency about the composition of the search committee. All SD/CD searches are under the oversight of the DDIR.

Appendix

Information that should inform the Review Committee:

- IC-specific expectations of SD/CD based on the general expectations listed above.
- Information on how the SD/CD was appointed and their appointment length.
- From the SD/CD, an up to 10-page narrative addressing how each of the elements defined by the IC (scientific management, administrative management, EDI management and ethical leadership) are being addressed.
- Summary reports for each IRP division that are being reviewed. This should include any existing Site Visit reviews of leadership, NEC Reports, or Blue-Ribbon Panel reports in ICs where these have occurred in the last 6 years.
- Reports from the EO and head AO specifying any persistent areas related to leadership that need improvement.
- Information regarding resources under the control of the SD/CD and how those resources were allocated. Specifically, the report should show budget and space allocations to PIs, Clinical Center, new initiatives, collaborative grants, equipment, training, infrastructure projects and new hires. Demographic information should be included for all these categories.

- Anonymous feedback solicited from trainees and other scientific staff (including all PIs) about the performance of the SD/CD as a survey and by requesting that anonymous comments be sent to the chair of the review committee (not to be shared with the SD/CD).
- PI hiring decisions, information regarding search, candidates considered, demographics and how final selection was reached.
- A summary of the career trajectory of previous fellows for up to the preceding 6 years of tenure of the SD/CD.
- A summary of the career trajectory of investigators that were denied tenure or left the IC since the last review as well as information regarding any retention efforts.
- Copies of presentation documents made to the NEC and the final NEC reports for the IRP within the past 6 years.