

Current Peer Review Process in the Office of Biotechnology Products

At the May ACPS meeting, we would like to discuss our interest in establishing a Peer Review process within CDER that will replace most, if not all, of the current system. The new system, if designed appropriately, could be utilized for evaluating all of CDER's intramural research programs. It should incorporate the best attributes of the current CBER system while being tailored as necessary to suit the needs of CDER.

At this time, the Office of Biotechnology Products continues to use the peer review system that was established in the Center for Biologics Evaluation and Research (CBER) for assessment of members of the research-review staff. This system is comprised of essentially three separate but interacting programs: the Promotion and Conversion Evaluation Committee, the External Site-Visit Review Program, and internal program monitoring. Each of these components is summarized in the outline below.

I. Promotion and Conversion Evaluation (PCE) Committee

Purpose:

To make recommendations to Management concerning requests received to:

- Convert Staff Fellows to permanent research/regulatory positions
- To promote permanent research/regulator scientists to the next grade level

The PCE committee offers at least two advantages:

- Highly scientific and technical positions are evaluated by scientists familiar with the nature of the activities being performed
- The scientific community can have greater confidence in the decisions made by peer scientists, and so more readily accept those decisions.

Guidance:

- General guidance provided by the CBER “Guide for the evaluation of research/regulatory scientists from GS-13 to GS-15” – **Attachment A** (Currently undergoing revision to update/clarify requirements).
- Office of Personnel Management's Research Grade Evaluation Guide from the General Schedule Position Classification Guides (Attachment B) is used to evaluate packages for promotion of principal investigators. Promotion is based on a predetermined total point value assigned by Workforce Compensation and Performance Service for the following factors:
 - The research situation, or assignment
 - Supervision received
 - Guidelines and originality
 - Qualifications and scientific contributions

- Summary information concerning the publication records of personnel.
Information collated includes:
 - Number of publications (mean, maximum, & minimum) for each GS level
 - Number of 1st & last author papers
 - Number of reviews, book chapters, etc
- Official report from an external review (Site Visit) of the scientific program
 - SV required within 2 years for conversion/tenure of Principal Investigator
 - SV required within 4 years for promotion of Principal Investigator
 - SV of PI required for promotion/conversion of Staff Scientist

Committee Members:

Two appointed tenured Principal Investigators (Researcher/Reviewer) from each of the following offices having ongoing research programs:

- Office of Vaccines Research and Review, CBER
- Office of Blood Research and Review, CBER
- Office of Cell, Tissue and Gene Therapy, CBER
- Office of Biotechnology Products, CDER

One full-time reviewer from one of the above offices

One member from personnel (OMS)

One representative from CBER OD

Ad Hoc Members:

One tenured Staff Scientist from each of the four offices listed above

II. External Scientific Review (Site Visit)

Frequency: Every 4 years (ideally)

Site Visit Committee:

- Chair - Member(s) of the Biologic Response Modifiers Advisory Committee (BRMAC); Chair is responsible for selecting committee members
- 1 or 2 external scientists with expertise in Researcher/Reviewer's field

Site Visit Format

- Committee provided with summary of scientific programs weeks in advance
- Overview of scientific program given by Center Director

- Statement by Office &/or Division Director regarding the specific program
- Presentations given by individuals undergoing review
- Closed committee session
- One-on-one meetings with subcommittees
- Closed committee session
- Final meeting with Division/Office/Center Directors to discuss conclusions
- Preliminary written report sent to Center Director/Associate Director for Research and provided to Division Director and scientists
- Ratification of the Site Visit Committee's report by the BRMAC (often preceded by summary presentations from the scientists who were reviewed)
- Copy of official report provided to the scientists, but remains confidential

Use of Site Visit Report

- For tenure/conversion – within 2 years of a site visit
- For promotion – within 4 years of a site visit
- For grant applications

III. Internal Program Monitoring

Occurs at Multiple Levels

- Lab Chief – Does not determine research focus, but does help assess research productivity, as well as ability to perform regulatory review
- Division Director – Discusses scientific productivity and regulatory abilities at progress meetings at least twice per year
- Office Director/Associate Director for Research – Assess scientific productivity via publications (frequency of publications, journal impact factor, # authors, etc.)