

§ 24.3 Policy Board.

The Secretary, or designee, may establish an SBRBPAS Policy Board to serve in an advisory capacity, recommending allocation of SBRBPAS slots among the participating operating divisions; assessing the administration of the SBRBPAS and ensuring consistent application of regulations, policies, and procedural guidelines; and recommending to the Secretary, or designee, changes to the Service as warranted. Membership will include representatives from the Office of the Assistant Secretary for Administration and representatives from the operating divisions which use the Service. The Secretary, or designee, shall determine the number of Board members; select the individual members, including the chairperson; and decide the length of service of each Board position.

§ 24.4 Eligibility.

(a) No individual may be appointed to the SBRBPAS unless such individual:

(1) Has earned a doctoral level degree in biomedicine or a related field, or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field; and

(2) Meets the qualification standards prescribed by the Office of Personnel Management for appointment to a position at GS-15 of the General Schedule.

(b) Individuals eligible under paragraph (a) of this section shall be experts outstanding in the field of biomedical research, clinical research evaluation, or biomedical product assessment. The criteria in paragraphs (c) through (e) of this section are indicators that the individual is considered an expert outstanding in their respective field.

(c) An individual will be considered an expert outstanding in biomedical research when the individual is actively engaged in original biomedical research, including behavioral research, and whose work in this area is considered by recognized experts or peers to be outstanding. One or more of the following achievements will indicate the individual has been recognized by experts or peers as outstanding:

(1) Conducted original research that has been published in peer-reviewed journals of high stature;

(2) Received major prizes and awards (such as visiting professorships and named lectureships) in recognition of original contributions to research;

(3) Received invitations to speak at or to chair major national or international meetings or symposia;

(4) Been elected to membership in professional societies of high stature; or

(5) Meet other criteria demonstrating sufficient rigor or accomplishment in a field that is relevant and necessary to the accomplishment of the agency's mission.

(d) An individual will be considered an expert outstanding in Clinical Research Evaluation when the individual is actively engaged in clinical research evaluation and is considered by recognized experts or peers to be outstanding. One or more of the following achievements will indicate the individual has been recognized by experts or peers as outstanding:

(1) Significant experience dealing with complex, precedent-setting evaluation issues, including those arising during product development, that involved significant scientific controversy, had far reaching implications for clinical research or resulted in a widespread economic effect in the health-care delivery system;

(2) Taken an active role in the development of significant scientific or regulatory guidelines for clinical research evaluation;

(3) Been the recipient of invitations to speak at or to chair major national or international meetings and symposia; or

(4) Meet other criteria demonstrating sufficient rigor or accomplishment in a field that is relevant and necessary to the accomplishment of the agency's mission.

(e) An individual will be considered an expert outstanding in biomedical product assessment when an individual is actively engaged in the development or assessment of biomedical products and whose work in this area is considered by recognized experts or peers to be outstanding. One or more of the following achievements will indicate the individual has been recognized by experts or peers as outstanding:

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(1) Significant experience dealing with complex, precedent-setting evaluation, scientific policies or development issues (*e.g.*, those associated with novel biomedical products, novel approaches to biomedical product-manufacturing, or use of novel evaluation methods);

(2) Demonstrated cutting-edge expertise in a scientific or technical discipline critical to design, development, manufacturing, clinical performance assessment, or other technical aspects of effective oversight of biomedical products;

(3) Played a leadership role in planning and conducting public meetings to seek public input and communicate regulatory scientific policies;

(4) Been the recipient of invitations to speak at or to chair major national or international meetings and symposia; or

(5) Meet other criteria demonstrating sufficient rigor or accomplishment in an activity or field that is relevant and necessary to the accomplishment of the agency's mission.

§ 24.5 Pay and compensation.

The Service is an ungraded system, with a single flexible pay range to include all members.

(a) Pay of SBRBPAS members is determined by the Secretary. A member's pay shall not be less than the minimum rate payable for GS-15 of the General Schedule and shall not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3 of the U.S. Code. Although the full pay range will be implemented, pay at the higher end of the range will be used only as needed to recognize individual scientific value and expertise as is necessary to recruit and retain exceptionally well-qualified scientists and technical experts.

(b) The following factors will be used in setting pay for individual members:

(1) Impact of the individual on the field of biomedical research, clinical research evaluation, or biomedical product assessment;

(2) Recognition of the individual by his or her peers in the respective field;

(3) Originality of the individual's ideas or work products;

(4) Specific clinical or highly technical skills of the individuals which are of benefit to the agency and which are in addition to requirements of the basic scientific assignment;

(5) The individual's earnings and monetary benefits; and

(6) Other relevant factors.

(c) Annual adjustments to pay rates may be made effective on the first day of the first pay period on or after January 1 of each calendar year. The rate of such adjustments will be at the discretion of the Secretary, or designee, except that the minimum rate payable in the SBRBPAS will be increased to the amount of the minimum rate of the GS-15 of the General Schedule.

(d) Other pay adjustments may be made by the Secretary or designee on an individual basis.

(e) New appointees to the SBRBPAS, who are not covered by the Civil Service Retirement System, will be covered by the Federal Employees Retirement System.

§ 24.6 Performance appraisal system.

The members of the Service shall be subject to a performance appraisal system that is designed to encourage excellence in performance and shall provide for periodic and systematic assessment of the performance of members.

§ 24.7 Inapplicability of provisions regarding appointments.

(a) Appointments to the Service shall be made without regard to the provisions of title 5 of the U.S. Code regarding appointments.

(b) Members of the Service shall not be covered by the following provisions of title 5 of the U.S. Code:

(1) Subchapter I of chapter 35 (relating to retention preference in the event of reduction in force);

(2) Chapter 43 (relating to performance appraisal and performance-based actions);

(3) Chapter 51 (relating to classification);

(4) Subchapter III of chapter 53 (relating to General Schedule pay rates); and

(5) Chapter 75 (relating to adverse actions).