

# CHARTER OF THE ASA BIOPHARMACEUTICAL SECTION

(Organized 1981)

## ARTICLE I. NAME

The name of this organization is the Biopharmaceutical Section of the American Statistical Association (hereafter called the Association).

## ARTICLE II. SCOPE

The special interest of the Biopharmaceutical Section is the application of statistics to the development and use of therapeutic drugs and devices in humans and animals.

a. Primary interests of this Section are:

- (i) the biochemical and physical sciences involved with drug and device discovery, formulations, product development, and quality control;
- (ii) the biological sciences involved in evaluating drug and device safety and efficacy;
- (iii) experimental human and veterinary medicine in support of therapeutic drugs and devices;
- (iv) health promotion and disease prevention and intervention activities; and
- (v) drug toxicity and disease surveillance.

b. In pursuit of these primary interests the Biopharmaceutical Section shares with other sections an interest in:

- (i) the impact of federal policy on human and animal research;
- (ii) standards of design, evaluation, and reporting biochemical, biological, human, and animal health experimentation;
- (iii) basic biological and mathematical-biological research;
- (iv) ethics related to human and animal experimentation;
- (v) publication of research developments and results;
- (vi) continuing education programs (including but not limited to statistics) for statisticians and researchers working in these areas.

## ARTICLE III. FUNCTIONS

To support the interests specified in the above scope, the Section may perform any or all of the following functions, together with such others as are appropriate:

- a. assist in the advancement of knowledge in the sciences contributing to the fields of human and animal health;
- b. establish and maintain liaison and cooperation with other scientific and professional organizations;
- c. plan appropriate sessions on the use of statistics in the fields of human and animal health at ASA and other scientific meetings;
- d. establish and maintain liaison and cooperation with other sections of the Association;
- e. cooperate with government, academia, business, and industry in resolving important statistical issues;
- f. participate in the development of the quantitative aspects of public policy concerning health products and services research, and use;
- g. produce separate publications, either as monographs or as periodical bulletins, as needed;
- h. aid, by whatever special ways are appropriate, the general development of statistics and of the American Statistical Association;
- i. assist in the development of curricula and training programs for statisticians planning to consult with human and animal health scientists;
- j. provide continuing education for members of the Section through workshops and sessions at national meetings;
- k. serve as a resource for public and private groups or agencies with interests in fields of human and animal health;
- l. conduct and participate in other programs consistent with the scope stated above, in cooperation with other segments of the Association membership where appropriate.

#### **ARTICLE IV. MEMBERSHIP**

Membership in the Section shall include all members of the American Statistical Association who pay section dues. The membership year for each member of the Section shall coincide with the member's membership year in the Association

#### **ARTICLE V. MEETINGS**

The annual business meeting of the Section shall be held in connection with the annual meeting of the Association and shall be announced in advance, preferably in the printed program for that meeting. Business may also be conducted with section members by mail.

#### **ARTICLE VI. OFFICERS AND REPRESENTATIVES**

The officers of the Section shall consist of the Chair, Chair-elect, Program Chair, Program Chair-elect, Secretary-Treasurer and Publication Officer. The Section shall also have one or more Representative(s) on the Association's Council of Sections, the number to be determined by the Charter of the Council of Sections.

Terms of all the officers shall be one year except for the Secretary-

Treasurer and Publication Officer whose terms shall be three years. The terms of Representatives to the Council of Sections shall be as prescribed in the Charter of the Council of Sections. A Representative on the Council of Sections is eligible for immediate re-election only if not previously elected for a full term.

No officer shall be eligible for immediate re-election to the same office except the Secretary-Treasurer.

The Chair-elect and the Program Chair-elect shall automatically succeed the Chair and Program Chair, respectively, at the annual change of officers, which shall occur on January 1.

#### **ARTICLE VII. VACANCIES IN OFFICE**

If the office of Chair or Program Chair becomes vacant, the Chair-elect and Program Chair-elect shall become the Chair and Program Chair respectively, the terms extending through the following year. Vacancies in other offices and among representatives shall be filled by appointment by the Chair with the approval of the Executive Committee.

#### **ARTICLE VIII. EXECUTIVE COMMITTEE**

The Executive Committee shall consist of the officers and representatives of the Section and the immediate past Chair. Appointed members also may serve on the Executive Committee.

The term of office for the appointed members of the Executive Committee shall be three years. Openings shall be filled by appointment by the Chair-elect.

The Executive Committee shall manage the affairs of the Section. Actions taken by the Committee during the year and plans for future activities will be presented at the annual business meeting of the Section for discussion.

The Chair, with the approval of the Executive Committee, may designate committees or individuals to carry out functions of the Section. The Chair or Executive Committee may appoint committees containing persons who are not members of the Association.

#### **ARTICLE IX. TASK FORCE**

Formal relationships with groups outside the Association will at times be useful in pursuing the Section's interests and fulfilling its functions. In this regard the Chair, with the approval of the Executive Committee, may designate organizations, organizational components, or inter-agency committees as Task Forces of the Biopharmaceutical Section.

Use of Task Forces shall be subject to the following conditions:

- a. Task forces are intended to fulfill medium to long-term functions, and shall be established for short-term purposes only under exceptional circumstances.
- b. Each organization represented on a Task Force must be non-profit, and must include at least three Section members.
- c. Unless it obtains specific authorization from the Association's Board of Directors, a Task Force shall not be entitled to use general Association funds or facilities, represent its activities as functions of the American Statistical Association, or to use the Association name or related symbols in any context outside of its specific relationship with the Section.
- d. The Section shall not fund operational expenses of a Task Force. However, the Executive Committee may approve reimbursement of modest expenses incurred by designated Section representatives in attending meetings of the Task Force.
- e. A Task Force shall provide a written annual report to the Chair and Executive Committee. This report shall be summarized at the annual Section Business Meeting and made available to section members who request it. A continuing Task Force shall be reviewed at three-year intervals by a Section Committee appointed by the Chair. The Committee chair shall be a member of the Section Executive Committee who is not otherwise involved with the Task Force.
- f. A Task Force may be dissolved by the Chair, with concurrence of the Executive Committee. In such a case, the Chair shall provide a statement of cause in writing to the appropriate representative of the task force.
- g. A Task Force shall be established using a memorandum of understanding approved by the Chair and Executive Committee, and subscribed to by all participating groups. The memorandum shall specifically document items "a" through "f" listed above; and it shall indicate the particular purposes of the Task Force, how these will support Section objectives, and how the Task Force will function.

## **ARTICLE X. NOMINATION AND ELECTION**

The Section's immediate past Chair shall serve as Chair of the Nominating Committee. The Section's immediate past Program Chair will also serve on this committee. Two additional members of the Section, appointed by the immediate past Chair, shall serve on this committee.

Each year the Nominating Committee shall submit to the Secretary of the Association and the Section Chair at least two nominations for each position to be filled. The Association's general deadline for submission of nominations shall apply. In addition, any Section member nominated by petition of 25 or more members of the Section shall also appear on the annual ballot, provided that the petition is presented to the Secretary of the Association and the Section Chair within 45 days after the mailing date of the publication announcing the names of the candidates submitted by the Nominating Committee.

Balloting shall be carried out as part of the Association's annual mail ballot for electing Association and Section officers.

## **ARTICLE XI. AMENDMENTS**

Amendments to this charter may be proposed by the Executive Committee of the Section or by petition signed by at least 25 members of the Section and submitted to the Executive Committee. The proposed amendment shall be submitted to the members of the Section for mail vote at the time of the annual election of officers. If approved by a majority of members of the Section voting, the amendment is subject to the approval of the Association's Council of Sections. If approved by the Council, the amendment shall be effective immediately, unless otherwise specified in the amendment itself.