

[Company name]

# 2020 BIOP CHARTER: Suggested edits following scheduled review

[Document subtitle]

12-6-2020

## Summary of proposed edits to the Charter

1. Language throughout was simplified by referring to “the Section” instead of “the Biopharmaceutical Section” and “the Association” instead of “the American Statistical Association.” This is described in Article I: Name.
2. In Article II: Interests, an interest was updated to reflect impact on federal and international policy, whereas it previously noted only federal policy.
3. In Article III: Functions, an introductory sentence was added for clarity: “In support of the Section’s interests (objectives), the Section may perform any or all of the following functions, together with such others as are appropriate”
4. In Article V: Annual Business Meeting, edits were made for readability and to remain current (e.g., updated to refer to *published* program rather than *printed* program).
5. In Article VI: Edits were made to establish that officers are eligible for immediate re-election to the same office only if the officer had not been elected to a full term. (The previous version of the charter only stated this for the Council of Sections Representative.) Additional edits clarified the years of service associated with the Section Chair and Program Chair offices.
6. In Article VIII: Executive Committee, updated to clarify that all Executive Committee members, whether elected or appointed, may vote on official business of the Section, except for critical financial matters for which voting is limited to elected officers only.
7. In Article VIII: Executive Committee, updated to state that simple majority rule is applied to votes of the EC for official business of the Section. Also clarified the use of proxy vote.
8. In Article VIII: Executive Committee, description of meetings was updated to remove the specification of an EC meeting at ENAR and ASA BIOP-Regulatory-Industry conferences. Instead, stipulates 3 meetings with one occurring at the annual Association meeting (JSM). This reflects current practice.

## **Charter of the ASA Biopharmaceutical Section**

**Organized and Chartered in 1981**

**Charter Revised May 2018**

**Charter Revised (or use Charter Reviewed if there are no changes) May 2021**

### **ARTICLE I. NAME**

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

### **ARTICLE II. INTERESTS (OBJECTIVES)**

The special interest of the Biopharmaceutical Section is the application of statistics to the development and use of therapeutic drugs, biologics, devices, other medicines, and related technologies in humans and animals.

a. Primary interests of the Biopharmaceutical Section are:

- i. the biochemical and physical sciences involved with drugs, biologics, devices, other medicines, and related technologies;
- ii. discovery, formulations, product development, and quality control;
- iii. the biological sciences involved in evaluating safety and efficacy of therapeutic drugs, biologics, devices, other medicines, and related technologies;
- iv. experimental human and veterinary medicine in support of therapeutic drugs, biologics, devices, other medicines, and related technologies;
- v. health promotion and disease prevention and intervention activities;
- vi. and product 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 and international 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; ethics related to human and animal experimentation;
- iv. publication of research developments and results;
- v. continuing education programs (including but not limited to statistics) for statisticians and researchers working in these areas.

### **ARTICLE III. FUNCTIONS**

In support of the Section’s interests (objectives), 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 The Joint Statistical Meetings (JSM) and other scientific meetings, conferences, tutorials and webinars;
- d. establish and maintain liaison and cooperation with other sections, interest groups, outreach groups, and chapters 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 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;
- 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 Association who pay section dues.

Section dues are set by the officers of the Section and may be altered annually in consultation with the Treasurer of the Association.

The membership year for each member of the Section shall coincide with the member's membership year in the Association. All Section Executive Committee Officers, elected or appointed, must be members of the Association and the Section.

#### **ARTICLE V. ANNUAL BUSINESS MEETING OF THE SECTION**

An 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 published program for that meeting and on the Section's website. A review of activities, plans for future activities, a Treasurer's Report, and a Program Chair Report will be presented at this meeting. Additional business throughout the year may also be conducted with Section members by virtual meetings, mail or email.

#### **ARTICLE VI. OFFICERS**

Section officers must be members of the Section.

The officers of the Section shall consist of all elected positions: the Chair, Chair-elect, Past Chair, Program Chair, Program Chair-elect, Past Program Chair, Secretary, Treasurer, Publications Officer, and Council of Sections Representative(s) (number of Representative(s) to the Council of Sections determined by the Association's Council of Sections Governing Board).

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.

Terms of all the officers shall be one year except for the Secretary, Treasurer, and Publications Officer whose terms shall be three years. (Note: The arrangement for Section Chair and Program Chair roles assumes three years of varying service associated with the office: chair-elect, then chair, followed by past-chair.) The terms of Representatives to the Council of Sections shall be as prescribed in the Charter of the Council of Sections. An officer is eligible for immediate re-election to the same office only if not previously elected for a full term.

Any individual may not hold more than one office at a given time.

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

If the office of Chair or Program Chair becomes vacant, a previously elected Chair or Program Chair shall become the Chair or Program Chair respectively, the terms extending through the following year. Vacancies in other offices and among representatives shall be filled by a previously elected but not currently serving Section officer as appointed by the Chair. A vacancy will be created by an individual needing to resign one office as a result of being elected to two offices which overlap in their service periods.

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

The Executive Committee shall consist of the elected officers and appointed representatives of the Section. All members of the Executive Committee, whether elected officers or appointed members, may vote on official business of the Section. However, for *critical* financial matters, defined as any financial matter involving an increase in expenses of more than 10% of total Section budgeted expenses, voting is limited to elected officers only.

All votes taken by the Executive Committee shall be subject to the rule of simple majority. That is, a motion carries only if greater than 50% of the voting EC members votes in favor. Proxy voting, submitted in writing in advance of the vote, is allowed when Executive Committee members are unable to participate live in a meeting of the Executive Committee. Details on the process for proxy vote shall be specified in the Manual of Operations. The Manual of Operations shall be posted to the Section's website or otherwise accessible to Section members.

The Chair may create and designate committees, task forces or individuals to carry out functions of the Section. The Chair may appoint task forces containing persons who are not members of the Association in addition to Section and Association members.

Duties of appointed members and their committees shall be described in the Manual of Operations. The term of appointed members of the Executive Committee shall not exceed three years but reappointment is possible.

The Executive Committee shall manage the affairs of the Section and conduct meetings. At least 3 planned meetings must occur prior to October 31 during the calendar year, with one of them occurring during the annual meeting of the Association. Unplanned meetings may also be called by the Chair.

To hold an official meeting of the Executive Committee, a quorum (defined as 50% of officers) must be present at the meeting and an opportunity for discussion of matters requiring vote must be allowed. Formal motions and financial disbursements must occur during an official meeting of the Executive Committee.

#### **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 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 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 the Association's Director of Operations, 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 current Chair and Chair-Elect shall also 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 Section elected officer position to be filled. The Association's general deadline for submission of nominations shall apply. In addition, any Section member nominated by petition of at least 5 percent of the membership 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 as described in the Manual of Operations and consistent with the Association's balloting timelines.

Balloting shall be carried out as part of the Association's annual 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 5 percent of the membership of the Section and submitted to the Executive Committee. The proposed amendment shall be submitted to the members of the Section for a vote at the time of the annual election of the Association.