

MANUAL OF OPERATIONS
for the
BIOPHARMACEUTICAL SECTION

AMERICAN STATISTICAL ASSOCIATION

October 29, 1997

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COMPOSITION OF THE EXECUTIVE COMMITTEE

Section Officers

Chair
Chair-Elect
Secretary-Treasurer
Program Chair
Program Chair-Elect
Publications Officer

Previous Section Officer

Past Chair

Section Representatives

Representative(s) to the Council of Sections

Section Appointments

Executive Committee Appointees

COMPOSITION OF THE ADVISORY BOARD

Appointed Section Functions

Work Group Coordinator
Editor of *Biopharmaceutical Report*
Associate Editor of *Biopharmaceutical Report*
Webmaster
Electronic Mailing List Moderator
Liaison to the Midwest Biopharmaceutical Statistics Workshop
Liaison to the ASQC Conference on Applied Statistics

1. DESCRIPTION OF DUTIES - CHAIR

The Section Chair is the chief administrative officer of the Section and is responsible for the conduct of all Section business. The term of office for the Chair is one year. The responsibilities of the Chair include, but are not confined to, the following:

1.1 EXECUTIVE DUTIES

- a. Serves as the chief executive officer of the Section and handles all matters that arise between business meetings. On matters of import that occur between formal meetings, the Executive Committee should be consulted by telephone or mail and possibly asked to vote their approval or disapproval.
- b. Appoints individuals to represent the Section on ASA Committees as the need arises. The ASA office will inform the Chair as to Section vacancies on existing ASA Committees.
- c. Organizes and appoints ad hoc committees as needed. Periodically acquaints the Executive Committee members with ongoing business activities of the Section.
- d. Appoints temporary replacements for any Executive Committee members who are unable to attend to their duties. If permanent replacements are required, the Chair consults with the Executive Committee regarding them. These appointees serve until the next election.
- e. May designate, with the approval of the Executive Committee, organizations, organizational components, or inter-agency committees as Task Forces of the Section.

1.2 MEETING DUTIES

- a. Calls and presides over all Executive Committee Meetings. Three meetings should be held annually: in conjunction with the Joint Statistical Meetings, in conjunction with the Biometric Society/ENAR meeting, and a transition meeting in the fall. It is the Chair's responsibility to arrange accommodations for such a meeting; but the Section Secretary-Treasurer, local arrangement committee, or ASA headquarters may be called upon to assist. The date and location of the transition meeting will be determined by the Chair. The agenda for each meeting should be prepared (in collaboration with the Secretary-Treasurer) and sent to the committee at least three weeks prior to the meeting. Newly elected officers should be invited to the meeting in conjunction with the Joint Statistical Meetings which should always be scheduled in advance of the Section Business Meeting.
- b. Schedules, plans, and presides over the Annual Business Meeting of the Section held during the Joint Statistical Meetings. If the Chair is unable to attend the meeting, the Chair-Elect should be called upon to assist in carrying out these responsibilities:
 - (1) The scheduling of this meeting must be coordinated with the Association so as to avoid conflict with any Section session.
 - (2) The Section membership is notified of the scheduled business meeting via the program announcement in *Amstat News* and also through any scheduled general mailings through the Association office.

(3) The agenda of this meeting should be prepared in consultation with the Executive Committee and should include, but not be restricted to, the following:

- (a) Reading the minutes of the last business meeting (optional)
- (b) Report from at least one of the Representatives to the Council of Sections
- (c) A summary of Section activities throughout the year
- (d) Reports from all Committee Chairs
- (e) Introduction of officers for the coming year
- (f) Call for program suggestions for the next meeting
- (g) Any announcements, requests, etc., which have been presented to the Chair prior to the meeting
- (h) Report of the Executive Committee meeting
- (i) Report from Publications Officer
- (j) Call for any new business

c. Discuss with representative(s) to the Council of Sections any topic to be presented to the Council either to inform them of Section plans or to elicit comments and reactions to Section activities, accomplished or planned.

1.3 TRANSITION DUTIES

- a. Send a written, one-page, annual report of Section activities to the ASA office in January. Usually a reminder request for the report is sent from the ASA office.
- b. Prepare and transmit to the incoming Chair a list of Section committees, giving the charge and membership for each. This information may be requested by the ASA office in December or during the early part of the following calendar year.
- c. Update this description of duties if necessary.
- d. Review Section-related correspondence and other materials. Send copies to Secretary-Treasurer if not done previously.
- e. Transmit to the Chair-Elect (now incoming Chair) any material which will assure an orderly transition and assist the successor in understanding the duties of the Chair.
- f. Review duties of immediate Past Chair in order to prepare for new role.

2. DESCRIPTION OF DUTIES - CHAIR-ELECT

The Chair-Elect is a member of the Executive Committee and administratively assists the Section Chair. Duties include assuming the responsibilities of the Chair when necessary and generally assisting in conducting the ongoing business of the Section. The term of office is one year. The responsibilities of the Chair-Elect include, but are not confined to, the following:

2.1 EXECUTIVE DUTIES

- a. Appoints two members to 3-year terms on the Executive Committee. Members should be mature, experienced persons who are either proactive in seeking new pathways or implementors in carrying out tasks or projects. They should have sufficient professional stature so that they can seek out Section members' opinions or so that Section members might seek them out in order to express views and opinions. Also important are their breadth and depth of interest in areas relevant to the Section.
- b. Appoints committee members, committee Chairs and other appointees to replace those whose terms have expired to the Membership, Liaison, Continuing Education, Finance, Fellows Nominations and Student Paper Committees as specified in the committees' Charges.
- c. Appoints Work Group Coordinator, Associate Editor of *Biopharmaceutical Report*, Webmaster, and Electronic Mailing List Moderator as specified in their Description of Duties.
- d. Appoints two members to serve 3-year terms as Liaisons to the Midwest Biopharmaceutical Statistics Workshop and the Conference on Applied Statistics.

These appointments should be made in December with terms beginning the following January so as to coincide with the Chair-Elect's term as Chair. Consultation before selection with the Section Chair and other members of the Executive Committee is recommended.

2.2 MEETING DUTIES

- a. Attends the Section Executive Committee Meetings and the Section Annual Business Meeting. Assumes the Section Chair's meeting duties if the Chair cannot perform them.

3. DESCRIPTION OF DUTIES - SECRETARY-TREASURER

The Secretary-Treasurer is a member of the Executive Committee and is the Chair's aid in the conduct of Section business. The general duties of the Secretary-Treasurer involve the collection, maintenance, and dissemination of information pertinent to Section activities. The term of the Secretary-Treasurer is 3 years. The responsibilities of the Secretary-Treasurer include, but are not confined to, the following:

3.1 MEETING DUTIES

- a. Attend and participate in all Executive Committee meetings, business meetings, and other Section activities. This involves a minimum of four meetings a year: the Executive Committee meetings held during the Joint Statistical Meetings, the Biometric Society/ENAR Meeting, and the transition meeting; and the Business Meeting of the entire Section also held during the Joint Statistical Meetings.
- b. Participation in these meetings includes giving an oral report of the minutes of previous meetings and recording the minutes at the present meeting. The Secretary-Treasurer may also assist the Chair in preparing an agenda for each of these meeting.

- c. After review by the Chair (and other Executive Committee members, if desired), the final copy of the minutes of the Executive Committee should be sent to all members of the Executive committee and the ASA Executive Director within four to six weeks following the meeting.
- d. After review by the Chair (and other Executive Committee members, if desired), the final copy of the minutes of the business meeting and Executive Committee Meetings should be sent to all Executive Committee members, the ASA Executive Director, the editor of *Biopharmaceutical Report*, and the Publications Officer. This should be done within four to six weeks following the meeting.

3.2 CORRESPONDENCE DUTIES

Assist the Section Chair in correspondence activities. Official correspondence should be on Section stationery.

3.3 FILE MAINTENANCE DUTIES

Maintain the files of relevant Section documents. Such files should include at least the following:

- a. An updated version of the Section roster available through the ASA office.
- b. Charter of the Section (in ASA Directory unless recently updated).
- c. The names, addresses, telephone numbers and duration of terms of Executive Committee members, Section committee members and Chairs, additional Program Chairs, and Section Function appointees.
- d. Maintain and keep current the *Manual of Operations for the Biopharmaceutical Section*.
- e. Minutes of all the Executive Committee Meetings, Business Meetings, and Executive-Advisory Board Meetings.
- f. All Section correspondence.
- g. Other relevant Section documents and reports.
- h. Section financial assets and debits where applicable.
- i. Copies of agreements between the Section and any other scientific body and all reports relevant to this agreement.

3.4 ASSOCIATION DUTIES

- a. Transmit copies of any resolutions or motions to the relevant organization unless the Chair specifically assumes the responsibility for doing so.
- b. Deal with ASA headquarters personnel in matters pertaining to the financial needs of the Section, should they arise.

3.5 TRANSITION DUTIES

- a. Prepare an updated list of the Executive Committee including addresses and telephone numbers and distribute this list to the Executive Committee and the Executive Director of ASA.
- b. Promptly pass on all Section files to the newly appointed Secretary-Treasurer calling attention to matters requiring immediate action.
- c. Update this description of duties if needed.

4. DESCRIPTION OF DUTIES - PROGRAM CHAIR

The Program Chair is a member of the Executive Committee and is the Section's representative on Association Committees concerned with Section publications. The Program Chair is also a member of the Biopharmaceutical Section Student Paper Committee. The Program Chair's official term of office is from January through December of an Annual Meeting year. The work of this office begins in the spring of the preceding year. Those elected serve the first year as Program Chair-Elect and the following year as Program Chair.

The Program Chair is responsible for reporting to the Executive Committee on Section sessions for regional and national meetings. As a member of the ASA Program Committee, there are additional responsibilities to its Chair. The key to success of this office is planning and adherence to deadlines.

The Section normally sponsors sessions at the Biometric Society/ENAR Meeting and sessions at the Joint Statistical Meetings. The Program Chair may appoint Chairs for each of the sessions leaving the organization to the appointee or may, of course, chair one or more of these sessions. For both the Biometric Society/ENAR Meeting and the Joint Statistical Meetings, the Program Chair should start to plan as soon after the Joint Statistical Meetings as possible. Both meetings require tentative program outlines by December or early January. It is important to contact the appropriate meeting Program Chairperson early.

Spring Immediately after notification of election or appointment to this post, study the program for the current year's meeting for format and current topics. Contact the current Program Chair and Section Chair-Elect for general advice and suggestions of topics for invited paper sessions. Begin planning these sessions. Finally, contact the ASA Program Chair for your meeting to establish planning procedures and deadlines.

August Attend the Joint Statistical Meetings. Again, talk with the current Program Chair.

Attend the Program Committee Meeting with ASA staff to report on your preliminary plans, to coordinate these plans with other Sections, and to receive schedules and further instructions for next year's meeting. The schedule below approximates the one which will be used.

September to November	Secure final commitments from organizers on invited program topics and participants.
December	Send preliminary invited session descriptions to the ASA Program Chair.
January	Meeting in Washington, DC with Program Committee
February	Send final version of invited program session description to the ASA Program Chair and to the ASA office. Finalize plans for round table's.
March	Contributed papers will be received by the ASA office. All contributed papers satisfying procedural requirements will be accepted and an acceptance letter will be sent from the ASA office to each author. The ASA office will send the abstracts to the appropriate Sections. There are two types of contributed paper sessions: (1) the topic contributed paper sessions organized with five or six papers and two or one discussants and (2) those organized by you. For those organized by you, classify the contributed papers by topic; seven time slots constitute a full session. A minimum of five papers need to be included and the additional two slots of time can be used for papers or for discussants. Obtain a chair for each of the contributed paper sessions. Individual contributed papers may also be presented as poster sessions. After organizing the sessions, send the contributed program to the ASA office.
April	Review preliminary printed program sent by the headquarters office prior to publication in <i>Amstat News</i> .
June-July	Receive and review invited and contributed papers from authors. Report any omissions, withdrawals, or irregularities to the ASA Program Chair and to the national office. Contact Section Program Chair-Elect and pass on ideas which have been suggested but not used on current year's program.
August	Attend the Annual Meeting. Check on audio-visual needs and rooms well before each session. Visit each session, be prepared to assist as the need arises. Attend the Executive Committee Meeting and the Section Business Meeting. Prepare to report on the year's activities, including estimates of attendance at each Section session.
September	Review all Section-related correspondence and other materials including final report on year's activities and send copies to Secretary-Treasurer (if not done previously) and to incoming Program Chair.

5. DESCRIPTION OF DUTIES - PROGRAM CHAIR-ELECT

The Program Chair-Elect is a member of the Executive Committee and also serves a January through December term, working with the Program Chair as needed from January through August. Other duties begin as described for the Program Chair beginning in July, i.e., while still Chair-Elect. The Program Chair-Elect should also:

1. Send copies of all Section-related correspondence to the Secretary-Treasurer.
2. Update this description of duties (and the Program Chair's) when necessary.
3. Attend the meeting of the ASA Program Committee in August of the year serving as Chair-Elect. The purpose of this meeting is to begin planning the program for the following year's Joint Statistical Meetings. Those attending the meeting are: Section Incoming Program Chairs, other Program Chairs-Elect, and ASA staff.
4. Transmit to the incoming Program Chair-Elect any material which will assure an orderly transition and assist the successor in understanding the duties of the program Chair-Elect.

6. DESCRIPTION OF DUTIES - PUBLICATIONS OFFICER

The Publications Officer is a member of the Executive Committee and is the one link between the Section and the editorial Boards of ASA publications, bringing the concerns of the Section membership to the attention of the Editors and reporting their responses back to the membership.

This individual also chairs the Biopharmaceutical Section Communications Committee and serves as editor of the *Proceedings of the Biopharmaceutical Section*.

The Publications Officer represents the Section on the ASA Subcommittee of Section Publication Officers (subcommittee of the ASA Committee on Publications).

The term of office is for three years, beginning in January. Responsibilities of the Publications Officer are as follows:

1. Attend the Executive Committee meetings and the Section's Annual Business Meeting.
2. Attend the meeting of the ASA Subcommittee of Section Publication Officers held at the Joint Statistical Meetings.
3. Assist in reading and editing of articles for publication in ASA journals. Solicit, informally or formally, the views of Section members on manuscript review.
4. Work closely with the editor of the Section newsletter, *Biopharmaceutical Report*, Webmaster, and Electronic Mailing List Moderator to coordinate the publication of information of interest to the Section membership, making decisions as to which format best meets the needs of the Section and its membership.
5. Solicit articles on subjects related to the Section's area of interest from members of ASA for

publication in ASA journals and the newsletter.

6. Serve as editor of the *Proceedings of the Biopharmaceutical Section*.
7. Chair the Biopharmaceutical Section Communications Committee.
8. Submit relevant information for publication in *Amstat News*, including minutes of the Section business meeting and Executive Committee meetings, announcements of other Section activities, and other items of interest to the Section.
9. Send copies of all Section related correspondence to the Secretary-Treasurer.
10. Update this description of duties as needed.
11. Transmit to the incoming officer any material which will assure an orderly transition and assist the successor in understanding the duties of the Publications Officer.

7. DESCRIPTION OF DUTIES - REPRESENTATIVE TO ASA COUNCIL OF SECTIONS

The Representative to the Council of Sections is an ex officio member of the Section's Executive Committee. The term of the Representative is three years.

1. In order that the Representative can fulfill the intended liaison function, the Representative must be informed on Section activities, interests, and desires. This should be achieved through:
 - a. Attendance at Section Executive Committee and business meetings
 - b. Comprehension of the minutes of those meetings and other relevant Section correspondence.
 - c. Communications with the Section Chair.
2. In turn, the Representative is to keep the Executive Committee and Section membership informed on Council discussions and actions. This may be done through oral reports at business meetings or through written reports to the Section Chair. Both means of communication are encouraged.
3. The Representative is to keep the Council of Sections informed on any changes in Section administrative procedures. Such information is essential to the Council which has the responsibility to update the *Manual of Operations for Officers of Sections* annually.

8. DESCRIPTION OF DUTIES - PAST CHAIR

The immediate Past Chair remains a member of the Executive Committee for an additional year. The primary purpose is to maintain continuity and continued communication within the Executive Committee.

Other Duties and Responsibilities:

1. Provide all records and assistance essential to the transfer of the Section business to the incoming Chair, including names of persons likely to be cooperative and effective in conducting Section business.
2. Complete any activity that remains unfinished at the end of the year.
3. Attend Executive Committee meetings to report on progress of the above projects.
4. Send copies of all Section related correspondence to the Secretary-Treasurer.
5. Serve as the Chair of the Nominating Committee. Appoint two Section members to serve one-year terms on the committee during the Chair's tenure.
6. Update this description of duties if necessary.

9. DESCRIPTION OF DUTIES - APPOINTED MEMBERS

Appointed members of the Executive Committee are selected to give breadth and depth to the Executive Committee. Term of office is three years.

Besides being available for staff activities, appointed members serve several principal functions as follows:

1. Provide a sounding board for evaluation of policy proposals before the Executive Committee.
2. Serve on Section committees as appointed.
3. Explore new approaches to the regular program responsibilities of the Section by suggesting new meeting topics, speakers, and formats.
4. Seek to bring new people into the Section who will assume responsibility and develop as leaders in subsequent years.
5. Seek out the views of Section members with whom they are in contact and present or represent these views to the Executive Committee.

10. DESCRIPTION OF DUTIES - WORK GROUP COORDINATOR

The Work Group Coordinator is appointed by the current Section Chair-elect for a three year term when the previous Coordinator's term expires. The primary responsibility of this position is to coordinate the activities of the approved work groups. This is accomplished by:

1. Assembling and presenting a list of potential work-group topics to the Executive Committee for

their approval at the Annual meeting.

2. Maintaining a list of potential work-group members.
3. Proposing work group constituency including work group leaders.
4. Providing the charges to the work-group leaders.
5. Reporting the results of the efforts of the work groups to the Executive Committee at the Annual meeting and to other audiences as necessary.
6. Recommending sessions to the Program Chair for both the Biometric Society/ENAR and Joint Statistical meetings which reflect the efforts of the work groups.
7. Organizing roundtable luncheons at the Annual meetings, with special focus on current topics of importance and interest to the pharmaceutical industry. These roundtable luncheons can be used as potential "recruiting grounds" for future work-group members. The discussion leaders of these luncheons are natural candidates to serve as leaders if they lead to the formation of a work group.
8. Update this description of duties as necessary.

11. DESCRIPTION OF DUTIES - EDITOR *BIOPHARMACEUTICAL REPORT*

The main responsibility of this position is the coordination and production of the *Biopharmaceutical Report*. This entails a close working relationship with the Section Publications Officer. The term of office for the Editor is one year.

Responsibilities are as follows:

1. Consult with the Section's Chair, Publication Officer and Secretary/Treasurer to address issues resulting from the efforts to produce the publication.
2. Solicit articles and reviews of text and software from capable interested parties.
3. Edit potential articles, discussions, reviews and summaries for clarity and content.
4. Compile materials for each issue of the Report and prepare them for publication.
5. Determine the best process for publication. Manage all of the activities that lead to the final printing.
6. Review and make necessary corrections of the Report's publication draft.
7. Coordinate the activities of the Associate Editor and others who participate in this effort. Train the Associate Editor to become Editor the next year.

8. Participate in the Biopharmaceutical Section Communications Committee.

12. DESCRIPTION OF DUTIES - ASSOCIATE EDITOR *BIOPHARMACEUTICAL REPORT*

This position is appointed by the current Section chair-elect for a 1 year term of Associate Editor. At the completion of that year, the Associate Editor becomes the Editor. The main responsibility of this position is to assist the editor in the production of the *Biopharmaceutical Report* and to become familiar with the procedures for the coordination and production of the *Biopharmaceutical Report* so the individual can perform as Editor the following year.

Responsibilities are as follows:

1. Assist with the compilation of materials, editing, review, and production of the *Biopharmaceutical Report*.
2. Become familiar with the process of compiling and producing the *Biopharmaceutical Report*.
3. Participate in the Biopharmaceutical Section Communications Committee.

13. DESCRIPTION OF DUTIES - PAST EDITOR *BIOPHARMACEUTICAL REPORT*

After the completion of a term as Editor of the *Biopharmaceutical Report*, the outgoing editor serves an additional 1-year term as Past Editor of the *Biopharmaceutical Report*. As such, the past editor serves as an advisor to the Editor.

Responsibilities are as follows:

1. To advise the Editor of the *Biopharmaceutical Report* on the compilation of materials, editing, review, and production of the *Biopharmaceutical Report*.
2. Advise the Editor of the *Biopharmaceutical Report* on issues of its production, such as the best process to use.
3. Update this description of duties and the description of duties of the Editor and the Associate Editor, as necessary.

14. DESCRIPTION OF DUTIES - WEBMASTER

This position is appointed by the Chair-elect. The primary responsibility of the Webmaster is to coordinate all web publishing activities for the Section. The Webmaster also acts as the Section's representative to the ASA Council of Sections Electronic Communications Committee.

Duties are as follows:

1. Convert Section generated documents for web site publication, adding all appropriate links and other HTML code.
2. Keep the web site current.
3. Advertise and promote the web site to Section members.
4. Represent the Section to the ASA Council of Sections Electronic Communications Committee. Attend the annual meeting of the Section Liaisons to this committee held at the Joint Statistics Meetings. Report to the Section on policy statements from this Committee.
5. Seek out and add web site links to documents of interest to Section members.
6. Work closely with the Editors of the *Biopharmaceutical Report* in translating electronic copy of that publication to the web site.
7. Participate in the Biopharmaceutical Section Communications Committee.
8. Update this description of duties, as necessary.

15. DESCRIPTION OF DUTIES - ELECTRONIC MAILING LIST MODERATOR.

This position is appointed by the current the chair-elect. The Electronic Mail List Moderator is responsible for maintaining the Section mailing list ASABIOPHARM.

Duties are as follows:

1. Verify current membership in the Biopharmaceutical Section prior to a subscription taking effect. Periodically (approximately once a year) reconfirm section membership.
2. Ensure the Internet Service Provider bills are paid and submit them to the Section Treasurer for reimbursement.
3. Manage all technical issues involved with the list and the Internet Service Provider.
4. Scan all posts after the fact for violations of list policy. Remind individuals unintentionally violating list policy of the policy. Revoke subscriptions of individuals who repeatedly or intentionally violate list policy from the list.
5. Ensure that the names and e-mail addresses of subscribers are not released outside of the Biopharmaceutical Section Executive Committee.
6. Appoint one or more Associate Mailing List Moderators, who can assume the Moderator's responsibilities in the Moderator's absence.
7. When away from on-line access for more than a few days, make every attempt to ensure that an Associate Mailing list Moderator is available to moderate the list. If away from on-line access

for more than a week and an Associate Moderator is not available, queue messages until a moderator is available.

8. Maintain and update all list documentation and auto-reply messages.
9. Reply to all list queries.
10. Participate on the Biopharmaceutical Section Communications Committee.
11. Update this description of duties, as necessary.

**16. DESCRIPTION OF DUTIES - LIAISON TO THE MIDWEST
BIOPHARMACEUTICAL STATISTICS WORKSHOP (MBSW)**

This position is held by the MBSW immediate past-chair. The main responsibility of this position is to coordinate Section support for the planning, operation, and publication of the workshop.

Duties are as follows:

1. Work with the MBSW general session chair and co-chairs to select appropriate work sessions or papers to be included in the *Proceedings of the Biopharmaceutical Section*.
2. Work with the MBSW program and session chairs to ensure that papers selected for publication are suitable for publication in the *Proceedings of the Biopharmaceutical Section*.
3. Work with the Biopharmaceutical Section publication officer to make sure authors and papers are identified for publication.
4. Attend the ASA Biopharmaceutical Statistics Section business meeting to assure all communications are made.
5. Update this description of duties as necessary.

17. LIAISON TO THE ASQC CONFERENCE ON APPLIED STATISTICS

This position is appointed annually by the Section Chair-Elect after consultation with the ASQC general session chair. The main responsibility of this position is to coordinate Section support for this conference, which includes providing speakers for two 3-hour tutorials and a 2-day short course.

**18. COMMITTEE CHARGES - CHARGE FOR BIOPHARMACEUTICAL SECTION
NOMINATING COMMITTEE**

Composition: The Section's immediate Past Chair shall serve as Chair. The Section's immediate past Program Chair will also serve on the committee. Two additional members of the Section will be appointed by the Section Past Chair.

Appointment Term: Each member will serve a one-year term.

Charge: To increase Section Membership by informing potential members of Section activities and the benefits of membership.

Procedures Implied by Charge of the Section Nominating Committee

1. The committee will submit to the Secretary of ASA and the Section Chair at least two nominations for each elected position to be filled no later than March 1.
2. The committee will develop and manage a petition process which allows the following: within 45 days after the mailing date of the publication announcing the names of the candidates submitted by the Committee, a petition with 25 or more Section member signatures nominating a Section member for a position must appear on the annual ballot.
3. The committee will ensure that the correct ballot is used during the ASA annual mail ballot election.

19. COMMITTEE CHARGES - CHARGE FOR BIOPHARMACEUTICAL SECTION MEMBERSHIP COMMITTEE

Composition: The committee consists of a Chairperson and two Section members. They are appointed by the Section Chair-Elect and approved by Section Executive Committee.

Appointment Term: Members are selected by the Chair-Elect to serve a 3 year term to replace members whose terms have expired. Appointments should be arranged to allow for one replacement each year. The Committee Chair should be selected annually and have committee experience.

Charge: To increase Section membership by informing potential members of Section activities and the benefits of membership.

Procedures Implied by Charge of the Section Committee on Membership

1. The committee will monitor Section demographic statistics and periodically produce reports.
2. The committee will identify groups and organizations, both within and outside of ASA, with whom affiliations would be mutually beneficial.
3. The committee will propose recruitment strategies and techniques for Executive Committee approval.
4. The committee will develop and maintain recruiting materials.

5. The committee will monitor methods used by similar committees to increase membership.
6. The committee will help to design, implement and report on surveys and studies of member satisfaction in cooperation with group specifically assigned this task.
7. The committee will annually propose a budget for operating expenses.

**20. COMMITTEE CHARGES - CHARGE FOR BIOPHARMACEUTICAL SECTION
FINANCE COMMITTEE**

Composition: The committee consists of a Chairperson, two Section members and the Section Secretary-Treasurer. Members, except for the Secretary-Treasurer, are appointed by the Section Chair-Elect with the approval of the Section Executive Committee.

Appointment Term: Members are selected by the Chair-Elect to serve a 3 year term to replace members whose terms have expired. Appointments should be arranged to allow for one replacement each year. The Committee Chair should be selected annually and have committee experience. The Section Secretary-Treasurer will serve the duration of his/her elected term.

Charge: To raise, manage, and promote funds for establishing programs and activities which promote the interests of the Section and ASA.

Procedures Implied by Charge of the Section Finance Committee

1. The committee will raise funds by developing and implementing procedures for soliciting institutional and individual contributions and sponsorship of special events and activities.
2. The committee will manage funds by developing budgets and providing appropriate stewardship of funds.
3. The committee will approve disbursement of funds through the Treasurer after appropriate authorizations are obtained.
4. The committee will provide reports of activities to the Section Executive Committee and general Section membership.
5. The committee will support additional use of funds. Potential uses include:
 - sponsorship of speakers and guests at ASA meetings by supporting travel and other expenses;
 - providing scholarships and arrange internships and work-study programs for statistics students interested in biopharmaceutical applications;
 - sponsorship of activities related to the recruitment of students into the statistics profession in general and biopharmaceutical applications in particular;
 - provide seed money for relevant workshops, short courses and seminars;
 - support sabbaticals and professional exchange programs to enhance interest and

understanding of biopharmaceutical applications.

**21. COMMITTEE CHARGES - CHARGE FOR BIOPHARMACEUTICAL SECTION
COMMITTEE FOR ESTABLISHING LIAISONS WITH OTHER ORGANIZATIONS**

- Composition: Chairperson appointed by the Section Chair-Elect from the Section Executive Committee. Remaining members will be the Organization Liaisons. The liaisons are appointed by the Chair-Elect after obtaining agreement from the other organization. Where possible, liaisons will be Section members who are officers of the other organization.
- Appointment Term: Term for liaison is one year but multiple terms are allowed and encouraged. Term for Chair is one year.
- Charge: To promote interaction with other organizations which have interests and objectives in common with the Biopharmaceutical Section with the objective of jointly addressing issues, problems and opportunities which impact both organizations.

Procedures Implied by Charge of the Section Committee for Establishing Liaisons with Other Organizations

1. The committee will meet at least once each year and provide a progress report to the Executive Committee. An oral report will be given at the annual Section Business meeting.
2. The committee will arrange joint presentations and sessions of mutual interest with participants from both organizations.
3. The committee will proactively participate in the development and implementation of joint workshops or short courses which are of interest to both organizations.
4. The committee will provide statistical input on issues or projects of concern to the other organizations.

**22. COMMITTEE CHARGES - CHARGE FOR BIOPHARMACEUTICAL SECTION
COMMITTEE ON CONTINUING EDUCATION (CE)**

- Composition: The committee consists of a Chairperson and up to seven additional Section members. They are appointed by the Section Chair-Elect with the approval of the Section Executive Committee. Other Section members may attend planning meetings.
- Appointment Term: Term for all Committee members is one year but term may be renewed. Chairperson should be appointed annually.

Charge: To address the continuing education needs of the Section members by making recommendations to the ASA Advisory Committee on Continuing Education.

Procedures Implied by Charge of the Section Committee on Continuing Education

1. The committee will assess the continuing education needs of members of the Section.
2. The committee will identify and contract qualified instructors to secure their commitment to participate in the CE program.
3. The committee will monitor the development of CE proposals by identified instructors which will meet the ASA requirements for workshop, short course or tutorials.
4. The committee will develop innovative ways of providing for continuing education needs of professionals interested in the field of Biopharmaceuticals.
5. The committee will submit proposals which represent the interests of the Section to the ASA Advisory Committee on Continuing Education each September.

23. COMMITTEE CHARGES - CHARGE FOR BIOPHARMACEUTICAL SECTION FELLOWS NOMINATIONS COMMITTEE.

Composition: The committee consists of a Chairperson and at least two additional Section members. All members are appointed by the Section Chair-Elect with the approval of the Section Executive Committee.

Appointment Term: Term for all Committee members is one year but the term may be renewed. The Chairperson should be appointed annually.

Charge: To nominate Section members for Fellow of the American Statistical Association and to find individuals to act as sponsor and gather and submit the necessary petition to the American Statistical Association Committee on Fellows.

Procedures Implied by Charge of the Section Committee on Fellows

1. Each year the Committee will review the membership of the section to select potential nominations for Fellow.
2. From the list of potential Fellows, the Committee will select those individuals they want to put forward as candidates for Fellow.
3. The Committee will solicit individuals to act as sponsor and to gather the necessary information and recommendations to submit.
4. The Committee will submit the names of their nominees for Fellow together with the necessary

information and recommendations to the ASA Committee on Fellows by the deadline specified by the ASA Committee on Fellows.

24. COMMITTEE CHARGES - CHARGE FOR BIOPHARMACEUTICAL SECTION COMMUNICATIONS COMMITTEE.

Composition: The Committee consists of the Publications Officer as chair, the Editor and Associate Editor of the *Biopharmaceutical Report*, the Webmaster, and the Electronic Mailing List Moderator.

Charge: To encourage and coordinate the efforts of the Biopharmaceutical Section to communicate to its members and to oversee the Section's various media for communication, including the *Biopharmaceutical Report*, *Proceedings of the Biopharmaceutical Section*, web page, mail list, and reports in *Amstat News*.

Procedures Implied by Charge of the Section Communications Committee.

1. The Committee will oversee and coordinate the various publications of the Biopharmaceutical Section, including the *Biopharmaceutical Report*, *Proceedings of the Biopharmaceutical Section*, and Web page.
2. The Committee will determine the most appropriate media to use in communications with the Biopharmaceutical Section membership, including the various publications of the Section, *Amstat News*, the Section web site, the Section electronic mailing list, or other modes of publication.

25. COMMITTEE CHARGES - CHARGE FOR BIOPHARMACEUTICAL SECTION STUDENT PAPER COMMITTEE

Composition: The Committee consists of three members appointed by the Section Chair-elect. The terms on the Committee will be three years and the terms will be staggered so that one new member will be appointed each year. The Program Chair will also be a member of the Committee. The Committee Chair will be appointed from among the three appointed committee members each year by the Section Chair-elect.

Charge: To run the Biopharmaceutical Section Student Paper Competition each year.

Procedures Implied by Charge of the Section Student Paper Committee.

1. The Committee will announce and advertise appropriately the Biopharmaceutical Section Student Paper Competition each year by letter to the various schools with graduate programs in statistics and announcements in whatever publications are appropriate.
2. To review all papers submitted to the Biopharmaceutical Section Student Paper Competition and select the winners of the competition.

3. To present the awards to the winners of the Competition at the Biopharmaceutical Section business meeting.
4. To publicize the winners of the Competition in whichever publications are appropriate, such as *Biopharmaceutical Report* and *Amstat News*.
5. To maintain the rules for the competition. To periodically review those rules and recommend any proposed changes to the Biopharmaceutical Section Executive Committee.

CHARTER OF THE 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.