

# Manual of Operations

American Statistical Association

Biopharmaceutical Section

Last Updated	Change History
31-DEC-2022	<p>Added a responsibility for the Chair to lead and facilitate the proposal review of any new BIOP committee, along with proposal template in Appendix A.</p> <p>Added a responsibility for the Chair to facilitate transition between new elected officers and outgoing officers toward the end of each calendar year.</p> <p>Added languages to encourage at-large members to get more involved in BIOP committees.</p> <p>Added a section on Funding Committee, and include the funding request and report templates in Appendix B.</p> <p>Added JSM contributed poster award amount.</p> <p>Editorial edits were made throughout.</p>
31-DEC-2021	<p>Added to Secretary position the responsibility of backup to SurveyMonkey Manager.</p> <p>Added to Webmaster the responsibility of the maintenance of a listserv.</p> <p>Revised the use of Webex as a generic for web-based virtual meetings and used more general language, unless specifically referring to the section Webex account. Similarly, revised “teleconference” to allow for videoconference as well.</p> <p>Updated the monetary award amounts for the</p>

	Best Contributed Paper Awards, Student Paper Awards, and Scholarship Committee Awards. Revised the timing for the Student Paper award process.
31-DEC-2020	<p>Modifications for spring BIOP meeting, Nonclinical Biostatistics Working Group budget, added conflict of interest to award committees, removed reference to CBS which disbanded.</p> <p>Added sections on Next Generation Stewardship Committee and Leadership-in-Practice Committee.</p> <p>Added section on voting.</p>
31-DEC-2019	Major manual update of content and organization; removed committees that are no longer applicable and added new committees

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# 1 General Information

## 1.1 Manual of Operations

The Manual of Operations (MoO) is a document used to describe the responsibility and functions of all positions and committees of the American Statistical Association (ASA) Biopharmaceutical Section (BIOP). The manual is reviewed yearly by Executive Committee (EC) members for updates. All updates should be provided to the Past Chair for incorporation prior to the end of the calendar year. Updates should be provided preferably by the time of the Transition Meeting, but the Past Chair can set a later deadline, ideally by the end of November. Regardless of the deadline, the updated MoO should be posted to the section website and the Google Docs drive by the beginning of the calendar year.

## 1.2 Executive Committee Members

The EC consists of both elected and appointed positions. As defined in the Section Charter, the EC members are the official voting members of the Biopharmaceutical Section (BIOP) of the American Statistical Association (ASA). Elected and appointed positions are specified below:

### Elected Positions

- Chair
- Chair-elect
- Past Chair
- Secretary
- Treasurer
- Program Chair
- Program Chair-elect
- Council of Sections (COS) Representatives
- Publications/Communications Officer

### Appointed Positions

- At-large Members

## 1.3 Advisory Committee Members

Advisory Committee members are appointed members and can vote in an unofficial capacity. Advisory Committee members consist of the following positions:

- Editor (includes Past and Associate editors) – Biopharmaceutical Report
- Webmaster(s)
- Chairs and co-chairs:
  - Distance-learning
  - ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop (Workshop) Committee
  - Awards Committees
    - Contributed Presentation Award Committee

- Contributed Poster Award Committee
  - Student Paper Award Committee
- Fellows Nomination Committee
- Membership Committee
- Mentoring Committee
- Outreach Committee
- Scientific Working Group Committee
- Nonclinical Biostatistics Working Group
- Next Generation Stewardship Committee
- Leadership-in-Practice Committee
- SurveyMonkey Manager
- Podcasts
- Statisticians in Small Biotech
- Publications and Communications Committee
  - Led by the Publications/Communications Officer
  - Social Media Coordinator
  - Biopharmaceutical Report Editors
  - Webmaster
  - Distance Learning Committee Chairs
  - Podcast Chairs

#### 1.4 BIOP Meetings

There will be three Executive Committee business meetings held in each calendar year. The first meeting will be held in the spring (March) as a videoconference. The second meeting is held in person if possible, at the Joint Statistical Meetings (JSM) (July/August) with videoconference available for those who cannot attend in person. The final meeting (Transition Meeting) will be held at the Regulatory-Industry Statistics Workshop (September), if possible, with videoconference available for those who cannot attend in person.

#### 1.5 Operational Meetings

Additional operational meetings may be held by the Section Chair approximately monthly with a smaller group consisting of a subset of the EC. The subset will be determined by the Section Chair. The Chair has the option of inviting additional attendees to an Operational Meeting to address section business.

#### 1.6 Voting

Voting on various initiatives may take place in person at Executive Committee meetings or between meetings using SurveyMonkey by the defined Executive Committee members in (Section 1.2).

##### 1.6.1 Voting Eligibility

Voting eligibility is defined in the Section Charter. The Chair and Secretary will ensure the appropriate voting process is followed on official business of the Section.

### 1.6.2 Proxy Voting

Proxy voting is allowed when Executive Committee members are unable to participate in a scheduled meeting of the Executive Committee. The following operational details govern this process:

- The member's proxy vote shall be presented in writing in advance of the vote taking place.
  - The member's proxy vote shall be submitted in writing to the Chair and Secretary 12 hours prior to the meeting, provided all pre-read materials for the meeting were available 3 days prior to the meeting.
  - If all pre-read materials for the meeting were *not* available 3 days prior to the meeting, then the member's proxy vote shall be submitted by the start of the meeting in which the vote will take place.
- The member's proxy vote will be stated in the tallying of votes after the oral voting has taking place, for transparency to all Executive Committee members.
- The minutes will record which members voted in proxy.

Members voting in proxy have the option to include a brief statement to be read by the Chair during the discussion prior to the vote taking place in the meeting. This should be provided to the Chair and Secretary in adherence to the timing requirements for the written vote by proxy.

## 2 Executive Committee Position Descriptions

### 2.1 Chair

The BIOP Chair is the chief administrative officer of the section and is responsible for the conduct of all section business. The term of office is 1 year; however, the total appointment for the individual elected to the Chair-elect position is 3 years with Year 1 as the Chair-elect and Year 3 as the Past Chair.

#### 2.1.1 Executive Duties

- Serves as the chief administrative officer of the section and handles all matters that arise between business meetings
- Files all EC meeting agendas and meeting documents on the BIOP Google drive
- Liaises with other ASA section or committee chairs and ASA staff as needs arise
- Consults with the EC, when needed, outside of regular business meetings
- Consults with the COS representatives on any topics to be brought to the attention of the ASA Council to the COS
- Appoints individuals to represent BIOP on ASA committees and organizes/appoints ad hoc committees, as needed
- Appoints temporary replacements, to serve until the next election, for any EC members who are unable to attend to their duties
- Designates additional appointees or committees, when necessary
- Serves on the BIOP EC Elected Officers Nomination Committee
- Reviews the section charter during years when a formal review is planned (charter is

reviewed every 3 years and is managed by the COS representatives; last revised in May 2021)

- Represents BIOP for its sponsorship at the Regulatory-Industry Statistics Workshop
  - The Section Chair and the Industry Workshop Co-chair should set up regular communication. The Section Chair may attend workshop planning meetings including the steering committee meetings.
  - Provides opening remarks at the Workshop.
  - May conduct a “Meet the Section Chair” Roundtable Luncheon
- Propose new BIOP committees, as relevant, and facilitate EC’s review of:
  - Assess the proposals for completeness, benefit to the members, and value-added potential for the section
  - Send the proposal to EC members ahead of time (recommend 2 weeks prior)
  - Hold EC meetings to facilitate the evaluation of new proposal for approval

A template for a new BIOP committee proposal can be found in Appendix A.

- Facilitate transition between incoming elected officers and outgoing elected officers towards the end of each calendar year.

#### 2.1.2 Meeting Duties

- Organizes and presides over all EC meetings (Spring meeting, JSM meeting, Transition Meeting, and Operational Meetings). Responsible for providing a draft agenda to the EC and Advisory Committee (approximately 3 weeks prior to the meeting) for feedback and providing the final agenda and slides prior to the meetings (preferably 1 week prior to the meeting). The Chair is responsible for arranging the video/teleconference/call-in number and login information for the meetings. This responsibility may be delegated.
  - The Spring meeting will be a virtual meeting to be held in March using BIOP’s Zoom account.
  - The JSM meeting is, if possible, a face-to-face meeting held at JSM (typically on Monday morning JSM local time). In addition to the general responsibilities, when the meeting will have an in-person component, the Chair is responsible for selecting the room, food accommodations, AV and phone equipment, using the order form provided by the ASA meeting planner (form is typically provided in springtime).
  - The Transition meeting is a face-to-face meeting, if possible, typically held in the afternoon (1 – 5 pm) on the first weekday of the Workshop. The room and AV and phone equipment are arranged with the ASA Workshop meeting planner. Newly elected officers and newly appointed committee chairs and ad-hoc members for the next year should be invited to the meeting although their voting rights begin the next year.
  - The operational meetings are scheduled by the Chair and are conducted by



teleconference or a virtual meeting platform. The section has a Zoo account, but the Chair may choose to use other secure software. Typically attended by the Chair, Chair-elect, Past Chair, Treasurer, Secretary, and Publications/Communications Officer, but the attendees are at the purview of the Chair.

- Organizes and presides over the JSM BIOP Mixer and Business Meeting held at JSM (typically on the Tuesday evening of JSM from 5:30 p.m to 7:30 p.m). The Chair is responsible for selecting the room, AV equipment, and food/beverage using the order form provided by the ASA meeting planner (form is sent at the same time as the form for the EC meeting reservations). The Chair may consult with the Treasurer on the yearly food budget.
  - Notifies the section membership of the scheduled (date/time/location) Annual Mixer and Business meeting. Notification may be done through an announcement in Amstat News as well as through an email to the membership prior to JSM and/or a posting to the Community Information page.
- Conducts a slide presentation of section business during the year. The presentation should include an introduction of the EC (each individual separately) and appointed committee members (group) as well as the next year's elected EC members. A quick report by the Chair, Chair-elect, and Past Chair is presented. Additional announcements should be done for the section finances (by the Treasurer), newly elected BIOP fellows (by Fellows Nomination Chair), and for all award recipients (by each committee chair). Finally, announcements for any additional business or initiatives important for the membership can be presented. It is highly recommended to allow time for a Q&A by the membership to achieve the transparency that the business meeting seeks.

#### 2.1.3 Transition Duties

- Prepares a joint report with the Chair-elect of the BIOP activities throughout the year (Chair prepares this part) and upcoming activities for the coming year (Chair-elect prepares this part). The report is provided to the Biopharmaceutical Report Editor for inclusion in the next issue.
- Ensures that the Chair-elect is aware of Chair duties and discusses any business that needs to be passed on to the Chair-elect as well as location of any relevant documents and material
- Reviews duties of immediate Past Chair to prepare for new role

#### 2.1.4 Calendar of Activities

MONTH	CHAIR YEAR ACTIVITY
JAN	<ul style="list-style-type: none"> <li>● Make additional appointments as needed</li> <li>● Send out email about upcoming Spring meeting, ask for agenda items</li> </ul>

<b>FEB</b>	<ul style="list-style-type: none"> <li>● Ask for agenda items and attachments again</li> <li>● Send out details of the meeting and the draft agenda</li> <li>● Request count of attendees</li> </ul>
<b>MAR</b>	<ul style="list-style-type: none"> <li>● Send out final agenda</li> <li>● Chair Spring EC meeting</li> </ul>
<b>MAR - MAY</b>	<ul style="list-style-type: none"> <li>● Make JSM room/AV and phone/food arrangements with ASA</li> <li>● ASA should reach out as early as March – if not, reach out to ASA</li> </ul>
<b>JUN</b>	<ul style="list-style-type: none"> <li>● Call for agenda items for JSM EC Meeting</li> </ul>
<b>JUL-AUG</b>	<ul style="list-style-type: none"> <li>● Send out final agenda/attachments [invite newly elected officials as optional to begin transition process]</li> <li>● Chair JSM EC meeting</li> <li>● Chair Business Meeting/Mixer</li> </ul>
<b>SEP</b>	<ul style="list-style-type: none"> <li>● Call for agenda items for Transition Meeting</li> <li>● Give welcome speech at Regulatory-Industry Statistics Workshop</li> <li>● Chair Transition EC meeting</li> </ul>
<b>OCT</b>	<ul style="list-style-type: none"> <li>● Assist Past Chair with nominations slate</li> <li>● Ensure Treasurer has everything needed to submit budget no later than 31-Oct</li> </ul>
<b>DEC</b>	<ul style="list-style-type: none"> <li>● Prepare annual report article with incoming Chair (Chair-elect) for publication in the Biopharmaceutical Report</li> <li>● Follow-up with Chair-elect and other EC members on outstanding items</li> </ul>

## 2.2 Chair-elect

The BIOP Chair-elect assists the Chair with administrative duties and may assume the responsibilities of the Chair, when necessary. The term of office is 1 year; however, the total appointment for the individual elected to the Chair-elect position is 3 years with Year 1 as the Chair-elect and Year 3 as the Past Chair.

### 2.2.1 Executive Duties

- Appoints the industry co-chair for the following year's Regulatory-Industry Statistics Workshop (when the Chair-elect will be the Chair). This appointment needs to be completed very early in January so that the co-chair for the following year can be announced at the February Workshop Organizing meeting and participate in the current year's planning activities. It is recommended that the appointment be viewed as independent from the Chair's organization to avoid the potential appearance of conflict of interest and/or favoritism. Reviewing the candidate, prior to appointment, with the current Chair and Chair-Elect is also recommended. Ultimately the decision lies with the Chair-Elect.

- Appoints two At-large committee members for the following year. It is recommended to appoint individuals who have not served in the BIOP EC previously to foster growth and new ideas. In addition, historically At-large members who can bring connections within the broader ASA and/or from other organizations have benefited BIOP.
- Appoints committee chairs and co-chairs to replace chairs that are in their last year of service. Most appointments are for a 3-year term. NOTE: some committees have the responsibility of replacing open positions within the committee responsibilities. In these cases, the Chair-Elect should consult with the committee to ensure that a replacement will be named in a timely manner and offer assistance if the committee does not have candidates.
- Serves on the BIOP EC elected officers Nomination Committee
- Serves on the Outreach and Collaboration Committee

#### 2.2.2 Meeting Duties

- Attends the EC meetings and Annual JSM Mixer/Business meeting
- Assumes the Chair's meeting duties if the Chair cannot perform them
- Provides a Chair-elect report

#### 2.2.3 Transition Duties

- Engages with the outgoing Chair to ensure awareness of Chair-elect duties
- Reviews duties of Chair to prepare for new role
- Prepares a joint report with the BIOP Chair regarding the activities of the section throughout the year (Chair prepares this part) and activities for the coming year (Chair-elect prepares this part). The report is provided to the Biopharmaceutical Report Editor for inclusion in the next issue .

#### 2.2.4 Calendar of Activities

MONTH	CHAIR-ELECT YEAR
JAN	<ul style="list-style-type: none"> <li>● Appoint Regulatory-Industry Statistics Workshop Industry co-chair for the next year as early as possible (e.g., late in the year prior to Chair-elect year) so appointees can participate as part of the Workshop steering committee for the year prior to being co-chair.</li> </ul>
JAN - SEP	<ul style="list-style-type: none"> <li>● Reach out committee chairs and appointed positions to ensure they can fulfill their duties (January). Ask if they need any resources or committee members.</li> <li>● Make necessary appointments (try to complete by JSM or not later than the Transition meeting)</li> </ul>
MAR	<ul style="list-style-type: none"> <li>● Attend Spring EC meeting and present Chair-elect report</li> </ul>
JUL-AUG	<ul style="list-style-type: none"> <li>● Attend JSM EC meeting and presents Chair-elect report</li> <li>● Attend Business Meeting/Mixer and presents Chair-elect report</li> </ul>

<b>SEP</b>	<ul style="list-style-type: none"> <li>● Attend Transition EC meeting and presents Chair-elect report</li> </ul>
<b>OCT</b>	<ul style="list-style-type: none"> <li>● Assist Past Chair with nominations slate</li> </ul>
<b>DEC</b>	<ul style="list-style-type: none"> <li>● Prepare annual report article with Chair for publication in the Biopharmaceutical Report</li> <li>● Follow-up with Chair on outstanding items</li> </ul>

## 2.3 Past Chair

The BIOP Past Chair remains a member of the EC. The term of office as Past Chair is 1 year; however, the total appointment for the individual elected to the Chair-elect position is 3 years with Year 1 as the Chair-elect and Year 3 as the Past Chair. The primary purpose is to maintain continuity of knowledge, progress, decisions, and continued communication within the EC.

Additionally, the Past Chair serves as the Funding Committee chair and the Nominating Committee chair for the next year's ASA election slate. The Past Chair may also be invited (in the last quarter of the year to participate in the Lester R. Curtin Award Selection Committee.

### 2.3.1 Executive Duties

- Provides necessary documents and assistance essential to the transfer of BIOP business to the incoming Chair, including names of individuals likely to be cooperative and effective in conducting section business
- Works with the BIOP CoS Representatives to complete the annual CoS survey requesting information about activities from the past year.
- Serves as Chair for the Funding Committee. Past Chairs who are employees of the FDA and cannot serve as Chair of the Funding Committee will, in consultation with Chair and Chair-Elect, appoint a replacement Funding Committee Chair to fulfill this task
- Serves as the Chair of the BIOP EC Elected Officers Nominations Committee and submits election slate to ASA by 01-Nov, providing the information that will be requested by ASA. The ASA requires the following information:
  1. Provide the correct spelling of each candidate's name as she or he prefers it to appear on the ballot.
  2. Include the current work affiliation of each candidate.
  3. Confirm with each candidate that she or he is an ASA member and a member of the BIOP section.
  4. Confirm with each candidate that she or he is not holding another section officer position in the year of the election.
- Updates the Manual of Operations throughout the year, as needed, and provides a final version by the beginning of the next calendar year. This final version should be posted to the BIOP website as well as the Google Drive.

### 2.3.2 Meeting Duties

- Attends the EC meetings and JSM Mixer/Business meeting
- Provides a Past Chair report and Funding Committee report

### 2.3.3 Transition Duties

- Provides final Manual of Operations document to the webmaster for posting.

#### 2.3.4 Calendar of Activities

MONTH	PAST CHAIR YEAR
JAN	<ul style="list-style-type: none"> <li>● Report on ASA activities to new Chair and hand over duties</li> <li>● Complete CoS Annual Survey</li> </ul>
JAN - OCT	<ul style="list-style-type: none"> <li>● Seek Manual of Operations changes</li> </ul>
MAR	<ul style="list-style-type: none"> <li>● Attend Spring EC meeting, present Past Chair report, and present Funding Committee report</li> </ul>
JUL-AUG	<ul style="list-style-type: none"> <li>● Attend JSM EC meeting and presents Past Chair report</li> <li>● Attend Business Meeting/Mixer, present Past Chair report, and present Funding Committee report</li> </ul>
SEP	<ul style="list-style-type: none"> <li>● Attend Transition EC meeting, present Past Chair report, and present Funding Committee report</li> </ul>
OCT - NOV	<ul style="list-style-type: none"> <li>● Finalize nominations slate and submit to ASA by 01-Nov (ASA will prompt the Section to submit)</li> </ul>
DEC	<ul style="list-style-type: none"> <li>● Send updated Manual of Operations to webmaster for posting.</li> </ul>

## 2.4 Treasurer

The Treasurer is the Chair's aid in the conduct of section business for financial matters. The general responsibilities of the Treasurer involve the collection, maintenance, and dissemination of financial information pertinent to Section activities with the assistance of the Chair and ASA. The term of the Treasurer is 3 years.

#### 2.4.1 Executive Duties

- Reviews section finances throughout the year and notifies ASA of any discrepancies. Section finances include three parts of the Section's accounts: main account, Regulatory Industry Statistics Workshop, and the Nonclinical Biostatistics Working Group budget, including the biennial Workshop
- Reviews the role of section Treasurer as per [the guidance for section treasurers](#) provided by the ASA.
- Reviews and approves the Nonclinical Biostatistics Workshop budget. Provides a copy to the BIOP Section Chair for review and comment, but not approval.
- Forwards receipts to ASA and requests payments for approved funding requests and reimbursements to ASA. Includes Chair on communications to ASA for reimbursements.

- Reminds committee chairs during Spring EC meeting to provide information for competition awardees no later than 31-May. Obtains all awardees' contact info, presentation title, and award place from each committee chair. Submits ASA forms (electronic forms) for all competition award checks and certificates. Forms are submitted no later than 30-Jun each year Picks up award checks and certificates at the JSM service desk during JSM and distributes award checks and certificates to committee chairs for presentation at the JSM Business Meeting and Mixer
- Puts together the following year's budget for the Section and for the Nonclinical Biostatistics Working Group. These two budgets are separate. **The Treasurer submits both budgets to ASA online by 31-Oct.** Approval of the BIOP budget is needed by the BIOP EC. Approval of the Nonclinical Biostatistics Working Group budget needs approval by the NCBWG, but not the broader BIOP EC. It is preferable to get approval of the BIOP EC budget at the Transition meeting.
- Provides copies of both the submitted BIOP EC budget and the submitted NCBWG budget to the Chair for posting to the Google Drive in the folder with the information for the Transition Meeting.
- Serves as a member of the Funding Committee

#### 2.4.2 Meeting Duties

- Attends the EC meetings and JSM Mixer/Business meeting
- *At each meeting*, provides the Treasurer's report that includes spend-to-date compared to the approved budget
- Provides the end-of-year report for the previous year during the Spring meeting

#### 2.4.3 Transition Duties

- Submits the following year's budget to ASA
- Ensures the incoming Treasurer is aware of duties and coaches on responsibilities of the position prior to the end of the final year of duty
  - Engages incoming Treasurer on development of following year's BIOP budget and Workshop budget prior to or during JSM. Engagement should occur by November of the last year of the Treasurer's term.
  - Coaches incoming Treasurer on submission of budget to ASA
  - Introduces incoming Treasurer to the financial information and reports on [www.amstat.org](http://www.amstat.org)
  - Explains any recent policy decisions regarding finances

#### 2.4.4 Calendar of Activities

MONTH	TREASURER
MAR	<ul style="list-style-type: none"> <li>● Prepare financial reports (closing date no earlier than 28-FEB) to go out with pre-reads for Spring EC meeting</li> <li>● Attend Spring EC meeting and present Treasurer's report</li> </ul>

<b>APR</b>	<ul style="list-style-type: none"> <li>Reminds award committee chairs to provide information for competition winners no later than 31-MAY</li> </ul>
<b>JUN</b>	<ul style="list-style-type: none"> <li>Submits check and certificate information no later than ASA's deadline, typically 30-JUN, for competition winners to be awarded at JSM</li> </ul>
<b>JUL-AUG</b>	<ul style="list-style-type: none"> <li>Prepare financial reports (closing date no earlier than 15-JUL) to go out with pre-reads for JSM EC meeting</li> <li>Attend JSM EC meeting and presents Treasurer's report</li> <li>Attend Business Meeting/Mixer and presents Treasurer's report</li> </ul>
<b>SEP</b>	<ul style="list-style-type: none"> <li>Attend Transition EC meeting and presents Treasurer's report and proposed BIOP budget for following year</li> </ul>
<b>OCT</b>	<ul style="list-style-type: none"> <li>Submit BIOP budget to <a href="http://www.amstat.org">www.amstat.org</a> by 31-OCT</li> <li>Submit NCBWG budget to <a href="http://www.amstat.org">www.amstat.org</a> by 31-OCT</li> </ul>

## 2.5 Secretary

The Secretary is the Chair's aid in the conduct of section business. The general responsibilities of the Secretary involve the collection, maintenance, and dissemination of business pertinent to Section activities with the assistance of the Chair as requested. The term of the Secretary is 3 years.

### 2.5.1 Executive Duties

- Responsible for generating meeting minutes for all EC meetings and ensuring clear documentation in the minutes of all decisions, approvals, and action items
- Distributes draft meeting minutes to the EC no later than 4 weeks from the last EC meeting for review and incorporates comments prior to providing minutes for the next EC meeting or before the end of the year in final year duty
- Solicits EC and committee chairs for action item resolutions prior to the next EC meeting
- May assist the BIOP Chair with development of meeting agendas and documents
- May assist the BIOP Chair and Chair-elect with maintenance of names and contact information of EC and committee chairs and members
- Works with Webmaster to provide documents for upload to the BIOP website
- Assists BIOP Chair with any other documents or section business, as necessary, including the use of SurveyMonkey to collect EC votes on proposals not occurring during the 3 BIOP EC meetings.
- Serves as the backup to the SurveyMonkey Manager to maintain and utilize SurveyMonkey for members.

### 2.5.2 Meeting Duties

- Attends the EC meetings and records meeting minutes
- Attends the JSM Mixer/Business meeting
- Provides the Secretary's report that includes review of action items from previous meeting

#### 2.5.3 Transition Duties

- Provides final meeting minutes from the EC Transition meeting to the incoming Secretary prior to the end of the final year of duty and includes BIOP chair on that email correspondence
- Ensures the incoming Secretary is aware of duties and coaches on responsibilities of the position prior to the end of the final year of duty

#### 2.5.4 Calendar of Activities

<b>MONTH</b>	<b>SECRETARY</b>
<b>MAR</b>	<ul style="list-style-type: none"> <li>● Follow-up on any action items from previous meeting</li> <li>● Attend Spring EC meeting and present Secretary's report</li> <li>● Takes meeting minutes and documents decisions and action items during the EC meeting</li> </ul>
<b>APR-MAY</b>	<ul style="list-style-type: none"> <li>● Submits draft meeting minutes for review within 4 weeks after Spring EC meeting</li> <li>● Follow-up on any action items from previous meeting</li> </ul>
<b>JUL-AUG</b>	<ul style="list-style-type: none"> <li>● Attend JSM EC meeting and presents Secretary's report</li> <li>● Takes meeting minutes and documents decisions and action items during the EC meeting</li> <li>● Attend Business Meeting/Mixer</li> </ul>
<b>AUG-SEP</b>	<ul style="list-style-type: none"> <li>● Submits draft meeting minutes for review prior to Transition meeting</li> <li>● Follow-up on any action items from previous meeting</li> <li>● Attend Transition EC meeting and presents Secretary's report</li> <li>● Takes meeting minutes and documents decisions and action items during the EC meeting</li> </ul>
<b>OCT-NOV</b>	<ul style="list-style-type: none"> <li>● Submits draft meeting minutes for review within 4 weeks after the Transition meeting</li> </ul>
<b>DEC</b>	<ul style="list-style-type: none"> <li>● Provides final meeting minutes to the incoming Secretary and BIOP Chair before the end of the year during the final year of duty</li> </ul>



## 2.6 Program Chair

The Program Chair is the BIOP representative on the overall JSM Program Committee. The term of office is 1 year; however, the total appointment for the individual elected to the Program Chair-elect position is approximately 2 1/2 years with half year after election and Year 1 as the Program Chair-elect and Year 2 as the Program Chair. Some duties begin during the Chair-elect year. The Program Chair is also a member of the ENAR Program Committee for the meeting during the year as the Program Chair. The exact duties as a member of the ENAR Program Committee are determined by the ENAR Program Chair, , who will contact the Program Chair-elect. It is the Program Chair-elect's responsibility to work with the ENAR Program Chair for responsibilities and deadlines.

### 2.6.1 Executive Duties

- Attends Program Committee meeting at ASA headquarters in February
- Responsible for the JSM sessions, JSM continuing education short courses, and roundtables and adhering to the deadlines as determined by the JSM Program Committee Chair
  - Requests members to submit Invited Session proposals and determines the sessions for the allotted number of slots for BIOP; from the remaining proposals, chooses one or two to submit to the Invited Session competition pool
  - Recommends that authors of remaining proposals review proposed sessions and resubmit as candidates for Topic Contributed sessions
  - Follows JSM guidelines for organization of contributed paper sessions:
    - Topic contributed paper sessions consist of five speakers, made up of at least three presenters and, at most, two discussants; each speaker has 20 minutes to present
    - Sessions organized by the Program Chair as Regular Contributed sessions. For Regular Contributed sessions, the Program Chair:
      - Classifies the papers by topic for 7 speakers in each session
      - Obtain a chair for each of the contributed paper sessions
  - Writes letters of sponsorship to ASA in support of continuing education courses
- Provides a report during the EC meetings on the sessions, continuing education courses, and roundtables
- Receives papers submitted for the Student Paper Competition to ensure the papers are adequately blinded and meet all submission requirements
  - Works with the Committee Chair of the Student Paper Competition to determine submission requirements and process for blinding
  - Distributes blinded papers to the Committee Chair for the Student Paper Competition for evaluation
  - Ensures there is a dedicated session at JSM for the student paper winners

### 2.6.2 Meeting Duties

- Attends the EC meetings and JSM Mixer/Business meeting
- Provides a report at EC meetings on the numbers of session and roundtable submissions and number allotted, the number of topic contributed sessions, and the continuing education courses
- Ensures all sessions have adequate session chair coverage
- Ensures all session chairs understand and adhere to the times allotted for the session and each presenter

### 2.6.3 Transition Duties

- Ensures the incoming Program Chair is aware of duties and coaches on responsibilities of the position throughout the year once the Program Chair-elect has been determined for the following year

### 2.6.4 Calendar of Activities

MONTH	PROGRAM CHAIR YEAR
<b>DEC (CHAIR-ELECT YEAR)-JAN</b>	<ul style="list-style-type: none"><li>● Contributed papers received by the ASA office<ul style="list-style-type: none"><li>○ All contributed papers satisfying procedural requirements will be accepted and an acceptance letter will be sent from the ASA office to each author</li><li>○ ASA sends the abstracts to each Section Program Chair</li><li>○ Individual contributed papers may also be presented as poster sessions</li><li>○ Organize sessions and send the contributed program to the ASA office</li></ul></li><li>● Students may begin submitting papers for the Student Paper Competition</li><li>● E-mail blinded student papers to Student Paper Award Committee Chair</li></ul>
<b>FEB</b>	<ul style="list-style-type: none"><li>● Attend meeting with ASA Program Committee to finalize the JSM Program</li><li>● Send final version of invited program session descriptions to the ASA Program Chair and to the ASA office</li><li>● Continue to receive papers for Student Paper Competition</li></ul>
<b>MAR</b>	<ul style="list-style-type: none"><li>● Attend Spring EC meeting and presents report on JSM Program development</li><li>● Deadline for students to submit papers for Student Paper Competition</li></ul>
<b>APR</b>	<ul style="list-style-type: none"><li>● Review preliminary printed program sent by the ASA office prior to publication in <i>Amstat News</i></li><li>●</li></ul>

<b>JUN-AUG</b>	<ul style="list-style-type: none"> <li>● Receive and review invited and contributed papers from authors</li> <li>● Report any omissions, withdrawals, or irregularities to the ASA Program Chair and to the ASA office</li> <li>● Contact the Program Chair-Elect and provide ideas which have been suggested but not used on current year's program</li> <li>● Attend JSM and JSM EC meeting and presents report on JSM Program (may not be able to attend full EC meeting) <ul style="list-style-type: none"> <li>○ During JSM, check on logistics including audio-visual needs and rooms well before each session</li> <li>○ Visit each session and be prepared to assist as the need arises</li> </ul> </li> <li>● Attend Business Meeting/Mixer and present Program Chair report</li> </ul>
<b>SEP</b>	<ul style="list-style-type: none"> <li>● Attend Transition EC meeting</li> </ul>

## 2.7 Program Chair-elect

The Program Chair-elect assists the Program Chair on the overall JSM Program Committee. The term of office is 1 year; however, the total appointment for the individual elected to the Program Chair-elect position is approximately 2 1/2 years with half year after election and Year 1 as the Program Chair-elect and Year 2 as the Program Chair. Some duties begin after election and before the formal Chair-elect year.

### 2.7.1 Executive Duties

- Attends JSM orientation meeting in the year elected (prior to Chair-elect year) for introduction to the upcoming roles
- Organizes JSM roundtables for the JSM meeting held during Chair-elect year
- Attends JSM Program Committee meeting during JSM for the following year's JSM Program

### 2.7.2 Meeting Duties

- Attends the EC meetings and JSM Mixer/Business meeting
- Provides report on preliminary JSM Program planning
- Assists the Program Chair as needed

### 2.7.3 Transition Duties

- Ensures the incoming Program Chair-elect is aware of duties and coaches on responsibilities of the position throughout the year

### 2.7.4 Calendar of Activities

<b>MONTH</b>	<b>PROGRAM CHAIR-ELECT YEAR AND ELECTED YEAR</b>
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<b>JUL-AUG (ELECTED YEAR)</b>	<ul style="list-style-type: none"> <li>● Attend JSM Program Committee meeting for next year's planning</li> </ul>
<b>DEC (ELECTED YEAR)-FEB</b>	<ul style="list-style-type: none"> <li>● Roundtable topics/abstracts submitted to ASA office</li> </ul>
<b>MAR-JUN</b>	<ul style="list-style-type: none"> <li>● Attend Spring EC meeting</li> <li>● Continue organizing roundtables</li> <li>● Begin planning for following year's JSM by soliciting members for proposals <ul style="list-style-type: none"> <li>○ Request Publications/Communication Officer to put a reminder in AMSTAT news for June about submitting abstracts by deadline, or email via ASA mailing list to members</li> </ul> </li> <li>● Remain in contact with the Program Chair</li> <li>● Complete responsibilities outlined by the ENAR program chair (i.e. session ranking)</li> </ul>
<b>JUL-AUG</b>	<ul style="list-style-type: none"> <li>● Attend JSM and JSM EC meeting <ul style="list-style-type: none"> <li>○ Assist Program Chair as necessary during JSM</li> <li>○ Attend the ASA Program Committee Meeting to report on your preliminary plans, coordinate plans with other Sections, and receive schedules and further instructions for next year's JSM meeting</li> <li>○ May be asked by members to write letters of support for Continuing Education Courses</li> </ul> </li> <li>● Attend Business Meeting/Mixer</li> </ul>
<b>SEP-NOV</b>	<ul style="list-style-type: none"> <li>● Attend Transition EC meeting and provide a report on next year's JSM Program</li> <li>● Deadline for submitting letters of support for Continuing Education Courses by end of September</li> <li>● Secure final commitments from organizers on invited program topics and participants</li> <li>● Send preliminary invited session descriptions to the JSM Program Chair</li> <li>● Submit sessions for the invited paper competition slots</li> </ul>
<b>DEC</b>	<ul style="list-style-type: none"> <li>● Complete invited program</li> <li>● Begin receiving Topic Contributed Session plans and individual contributed paper abstracts</li> </ul>

## 2.8 Council of Sections (COS) Representatives

The COS representatives are the liaison between the ASA COS Governing Board (COSGB) and the BIOP EC. The general responsibilities of the COS representatives are to bring forward and communicate issues to and from the COS. The term of the COS representative is 3 years. The number of COS representatives within a section is determined by the size of the section.

Because most of the responsibilities for the COS representatives occur at JSM, it is important that candidates can commit to attending JSM for a 3-year term prior to running for COS representative. It is also critical for the COS representatives to request enough time on the agenda to present at the JSM BIOP EC meeting.

#### 2.8.1 Executive Duties

- Keep the Executive Committee and Section membership informed on Council discussions and actions
- Keep the Council of Sections informed on any changes in Section administrative procedures. Such information is essential to the Council that has the responsibility to update the *Manual of Operations for Officers of Sections* annually
- Keep abreast of ASA corporate initiatives and their impact on BIOP. Potential topics include:
  - Voting on new sections into the Council of Sections
  - Changes to JSM meeting structure
  - Requested charter updates from the Council of Sections Governing Board (COSGB) Vice-Chair. The BIOP charter must be updated at most every 3 years. The updates need to be submitted to the entire membership for approval as part of the annual ASA election process.
  - Policy issues to the statistics profession
  - Issues common to all sections
- Represent BIOP by voting on issues raised to the Council of Sections
- Brings issues to the BIOP Chair when not aligned in time near a scheduled EC meeting
- Establishment of communication with the COSGB Vice-Chair for BIOP
- Bringing issues forward to the Council of Sections from the EC, which require multi-section support
- Share BIOP events to the ASA as a whole

#### 2.8.2 Meeting Duties

- Attends the EC meetings and JSM Mixer/Business meeting
- Provides the COS report at the EC meetings
  - Provides EC an overview of the COS Sunday meeting at JSM
  - Poses questions to the EC requiring input back to the Council of Sections
- Attends Sunday and Thursday COS meeting at JSM
- Attends any other ad hoc meetings called by the Council of Sections or COSGB

#### 2.8.3 Transition Duties

- Ensures the incoming COS representative is aware of duties

#### 2.8.4 Calendar of Activities

<b>MONTH</b>	<b>COUNCIL OF SECTIONS REPRESENTATIVES</b>
<b>MAR</b>	<ul style="list-style-type: none"> <li>● Attend Spring EC meeting and present COS report</li> </ul>
<b>JUL-AUG</b>	<ul style="list-style-type: none"> <li>● Attend JSM COS Sunday meeting</li> <li>● Attend JSM EC meeting and presents COS report</li> <li>● Attend Business Meeting/Mixer</li> <li>● Attend JSM COS Thursday meeting</li> </ul>
<b>SEP</b>	<ul style="list-style-type: none"> <li>● Attend Transition EC meeting and presents COS report</li> </ul>

## 2.9 Publications/Communication Officer

The Publications/Communication Officer is the link between the Section and various channels of communication, bringing the concerns of the Section membership to the attention of the EC and reporting responses back to the membership. The term of the Publications/Communication Officer is 3 years.

### 2.9.1 Executive Duties

- Coordinates BIOP communications and ensures effective external communication and publications including but not limited to publications, event announcements and website posting through appropriate channels (Amstat News, Biopharmaceutical Report, website posting, email, social media, etc). awards
- Lead the effort to create a communication timeline guidance for each key activity. Note: the material should be submitted via email to the ASA publications office at least 6 weeks prior to the desired publication date (e.g. send to ASA by 20FEB for the April issue). To allow enough leadtime, contact author(s) of write-up(s) at least 3 weeks prior to the submission deadline.
- Guide the Communication Secretary to create and maintain the year-round communication plan and communication calendar for all communication/publication channels. Make sure enough lead time for all communication and publications. The next-year calendar should be created and shared at the Sept EC meeting
- Work with EC members to evaluate additional new information to communicate and the routes of communication
- Maintain regular communication with all Biopharmaceutical Section sub-committees to ensure precise and on-time announcements and postings. Key announcements may include but are not limited to conferences (MBSW, ENAR, NCB, FDA/DIA statistics forum, Deming conference, JSM, Regulatory-Industry Statistics Workshop), activities related to JSM (Student paper competition, poster awards, Mixer), webinars, podcasts, online (YouTube) videos, and executive meeting minutes. Some key activities and announcements are listed in this table:

<b>MONTH</b>	<b>ANNOUNCEMENTS and KEY ACTIVITIES</b>
<b>JAN</b>	Webinar topics and schedule, notes from incoming and outgoing chair

<b>FEB</b>	MBSW (Muncie) conference that takes place in May; ENAR conference that takes place in March
<b>MAR</b>	Biopharm Section sponsored conferences (e.g., NCB)
<b>APR</b>	FDA/DIA statistics forum
<b>MAY</b>	Deming conference
<b>JUN</b>	JSM announcements (including an announcement of the Business Meeting held in conjunction with the Mixer), contributed paper award winners for previous year (awards to be presented at upcoming JSM), notice to encourage everyone to fill out ballots at JSM Biennial Nonclinical Biostatistics Conference (odd years)
<b>JUL</b>	ASA fellow requests for next year, ask the Program Chair-elect for information regarding upcoming JSM submissions deadlines.
<b>AUG</b>	Regulatory-Industry Statistics Workshop (usually done by ASA publication office)
<b>SEPT</b>	* No announcements * (special ASA issue)
<b>OCT</b>	JSM student paper results, requirements for next year's student paper competition in <i>Amstat News</i> , section news for the year (post-JSM), announcements of Award recipients (Poster Awards, student paper awards)
<b>NOV</b>	Podcast updates and schedule, notice of Poster Award at next JSM (encourage submissions for the award)
<b>DEC</b>	Incoming/outgoing chair write-up, JSM student paper announcement for next year

Note: the material should be submitted via e-mail to the ASA publications office at least **6 weeks** prior to the desired publication date (e.g., send to ASA by Feb 20 for the April issue). To allow enough lead-time, contact author(s) of write-up(s) at least 3 weeks prior to the submission deadline.

### 2.9.2 Meeting Duties

- Attends the EC meetings and JSM Mixer/Business meeting
- Provides the Publications/Communication Officers report

### 2.9.3 Transition Duties

- Ensures the incoming officer is aware of duties and coaches on responsibilities of the position prior to the end of the final year of duty. This may include facilitating a meeting with the Biopharmaceutical Report editor, webmaster, Communication Secretary, Membership Committee chair, Social Media Coordinator, and committee chairs for distance-learning and the podcast

## 2.10 At-large Members

The At-large members are appointed members of the EC and have official voting privileges. The general responsibilities of the At-large members are to provide a perspective of issues of the BIOP membership and bring in new individuals into the section. The term of the At-large members is 3 years. Two new members are appointed each year by the Chair, and the first year of the 3 year term starts in the year that the Chair who appointed them serves as Chair. At-large members are highly encouraged to seek out additional roles in BIOP, such as becoming chair or member of BIOP committees, to be further engaged in BIOP business activities for service of the BIOP members.

#### 2.10.1 Executive Duties

- Provide a sounding board for evaluation of policy proposals before the EC
- Explore new approaches to the regular responsibilities of BIOP by suggesting new meeting topics and speakers
- Seek to bring in new individuals into BIOP who will assume responsibility and develop as leaders in subsequent years
- Seek out views of BIOP members with whom they are in contact with and represent these views to the EC
- Participate and/or lead new initiatives for EC

#### 2.10.2 Meeting Duties

- Attends the EC meetings and JSM Mixer/Business meeting

#### 2.10.3 Transition Duties

- Ensures the incoming At-large members are aware of duties

#### 2.10.4 Calendar of Activities

<b>MONTH</b>	<b>AT-LARGE MEMBERS</b>
<b>MAR</b>	<ul style="list-style-type: none"> <li>● Attend Spring EC meeting</li> </ul>
<b>JUL-AUG</b>	<ul style="list-style-type: none"> <li>● Attend JSM EC meeting</li> <li>● Attend Business Meeting/Mixer</li> </ul>
<b>SEP</b>	<ul style="list-style-type: none"> <li>● Attend Transition EC meeting</li> </ul>

## 3 Advisory Committee Position Descriptions

### 3.1 Funding Committee

The Funding Committee is charged to review funding request and determine the justification for such request first. The Funding Committee then brings funding request to BIOP EC for voting to approve or disapprove a funding request. The committee is served by the Chair, who is the BIOP past chair for the calendar year, Treasury, and 1-2 additional members.



The process for funding request is as follows:

- Funding requester submits a funding request form (see template in Appendix B)
- Funding committee chair reviews the funding request and brings it to BIOP EC for voting.
- If approved, Treasurer working with ASA, facilitates the funding transfer to the requester's professional organization.
- The funding requester should submit a report on the use of the fund (see template in Appendix B)

For our record, at the 2020 JSM EC meeting, EC discussed the proposal to approve the annual funding request for Meeting Within a Meeting (MWM), which is a forum for Professional Learning for Teaching Middle- and High-School Statistics. The funding request was approved by EC at the 2020 JSM as annual funding of \$2500 each year.

### **3.2 Biopharmaceutical Report Editors**

The general responsibilities of the Biopharmaceutical Report editors are the coordination and production of at least two editions of the Biopharmaceutical Report within the year. The term of office is 1 year; however, the total appointment for the individual appointed to the Associate Editor position is 3 years with Year 1 as the Associate Editor, Year 2 as the Editor, and Year 3 as the Past Editor.

#### **3.2.1 Editor Duties**

- Consults with the EC to address issues resulting from the efforts to produce the publication
- Solicits news articles related to BIOP business, including upcoming conference information, minutes of EC meetings, summaries of finances, and lists of award winners (e.g., paper and poster competition winners, student paper awards, scholarship recipients, and new fellows)
- Solicits articles of interest to the section membership, which could include methodological surveys, interesting applications, or reviews of texts or software, from capable interested parties
- Send a reminder to the Chair and Chair-elect at the end of the year to provide a transition article (see more info in Section 2.1.3).
- Reviews and edits articles for clarity and content
- Compiles materials for each issue of the Report and prepares them for publication
- Coordinates with others (e.g., the Webmaster, ASA's publishing support staff), as appropriate, for publication and distribution of the Report
- Reviews and makes necessary corrections of the Report's publication draft and submits the final product for distribution
- Works with Webmaster to ensure that the Report is published on the website
- Coordinates the activities of the Associate Editor and others who participate in this

effort

- Attends EC meetings and provides updates
- Trains the Associate Editor to become Editor the next year
- Build communication strategy for this committee by working with the Publication Officer and Communication Secretary. Communicate key events through appropriate communication channels through the Webmaster and Social Media Coordinator.
- Assist the Chair-Elect with recruiting future editors.

### 3.2.2 Associate Editor Duties

- Assists the Editor with the compilation of materials, solicitation of articles, editing, review, production, and distribution of the *Biopharmaceutical Report*
- Becomes familiar with the process of compilation and production of the *Biopharmaceutical Report*

### 3.2.3 Past Editor Duties

- Advises and assists, as needed, the Editor on the compilation of materials, solicitation of articles, editing, review, production, and distribution of the *Biopharmaceutical Report*

## 3.3 Webmaster

The primary responsibility of the Webmaster is to coordinate all web-publishing activities for BIOP. The term of the Webmaster is 3 years.

### 3.3.1 Webmaster Duties

- Converts Section-generated documents for website publication, adding all appropriate links and other HTML code
- Keeps the website current updating the following information as needed:
  - Names, addresses, telephone numbers, and duration of terms of EC and committee chairs and maintains a Google Group with this information for use of EC members
  - Link to current *Biopharmaceutical Report*
  - Award winners posted after JSM
  - Announcements and activities
  - Minutes of meetings, as appropriate
  - Corporate sponsors, if any
  - Scientific working groups
- Ensures membership list is updated
- Advertises and promotes the website to BIOP members
- Verifies links to and from ASA sites and other applicable webpages
- Attends EC meetings and provides updates
- Works with the Publication Officer

### 3.3.2 Website Maintenance Activities

Section	REGULAR WEBSITE MAINTENANCE
<b>Main Page</b>	<ul style="list-style-type: none"> <li>● Check monthly</li> <li>● <b>Biopharmaceutical Section News</b> <ul style="list-style-type: none"> <li>○ Update information about Workshop quarterly (proposals, registration, etc.)</li> <li>○ Update other major items (award submissions, competitions, non-clinical biostatistics conference, upcoming webinars)</li> </ul> </li> <li>● <b>What's New</b> <ul style="list-style-type: none"> <li>○ Update podcast (typically one per month)</li> <li>○ Update Biopharm Report</li> </ul> </li> </ul>
<b>About Us</b>	<ul style="list-style-type: none"> <li>● Update quarterly</li> <li>● <b>Related links</b> (yearly) – check that links work. Consider other additions (such as sections or working groups with synergy with BIOP)</li> <li>● <b>Join</b> (yearly) – check that links work</li> <li>● <b>Subcommittees</b> (yearly) – follow up if any changes are needed</li> <li>● <b>ASA Fellows</b> (yearly after JSM) – add new members</li> <li>● <b>Executive Committee</b> (yearly after transition meeting)</li> <li>● <b>Charter</b> (when updated)</li> <li>● <b>History</b> (add new chair to list of Biopharmaceutical Section Chairs)</li> </ul>
<b>Working Groups</b>	<ul style="list-style-type: none"> <li>● Update members and tasks after transition meeting or when the group is initially formed</li> <li>● Maintain template page to be used by new groups to population website</li> </ul>
<b>Events</b>	<ul style="list-style-type: none"> <li>● Update as needed</li> <li>● <b>Archived Webinars</b> (yearly, after transition meeting) – post abstract, presenters and PDF of slides</li> <li>● <b>Biopharmaceutical Event Calendar</b> (as needed) – as events of interest for the section arise, add event title, dates, location and link to main page</li> <li>● <b>Nonclinical Biostatistics Conference</b>, biennially. Need content from Nonclinical Working Group</li> </ul>
<b>Podcast</b>	<ul style="list-style-type: none"> <li>● Update monthly or as needed</li> <li>● Post new podcasts. Be sure to update What's New on main page</li> </ul>
<b>Biopharm Report</b>	<ul style="list-style-type: none"> <li>● Post new Biopharm Report and update What's New on main page</li> <li>● Update editors (yearly)</li> </ul>

<b>Awards</b>	<ul style="list-style-type: none"> <li>• Update yearly</li> <li>• <b>Student Paper Competition</b> (yearly, fall) – to advertise to Universities. Get update from student paper award committee chair</li> <li>• <b>Past Award Winners</b> (yearly, after JSM and Regulatory-Industry Statistics Workshop) – get updates from contributed paper, student paper, and contributed paper award teams, including PDFs of posters</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Biopharmaceutical Section Scholarship Award</b> (yearly in fall) – Need to update the name and address for the chair of the Scholarship Award Committee for submissions</li> </ul>

### 3.4 Distance Learning Committee

The responsibilities of the Committee Chair are to coordinate all activities relating to the selection of distance learning opportunities and the running of the webinars. The term of the Committee Chair is 1 year. Additionally, the committee has two other members.

#### 3.4.1 Committee and Chair Duties

- Solicit and suggest topics of interest to the membership and identify speakers who could provide a valuable learning experience
- The chair leads the committee in deciding which topics and speakers to select, the contact of the speakers, and all details regarding the arrangement of learning experience, coordinating with the ASA Office, as appropriate, to deal with scheduling, pricing, technical arrangements (including arrangements for archiving), etc.
- The chair is responsible for assuring that upcoming learning opportunities are announced
- Works with the ASA's Education Programs Administrator in coordinating the distance learning event
- The chair attends EC meetings and provides updates on the webinars with respect to the number of attendees
- Ensures the incoming chair are aware of duties
- Build communication strategy for this committee by working with Publication Officer and Communication Secretary. Communicate key events through appropriate communication channels through webmaster and Social Media Coordinator.
- Assist the Chair-Elect with recruiting future committee members. Propose a committee member to be the Committee Chair for the next year.

#### 3.4.2 Calendar of Activities

<b>TIME RELATIVE TO WEBINAR</b>	<b>TASK (MANY TASKS ARE FACILITATED BY THE ASA'S EDUCATION PROGRAMS ADMINISTRATOR)</b>
<b>6-12 months in advance</b>	<ul style="list-style-type: none"> <li>• Identify potential topics/theme and speakers (e.g., Bayesian Methods, Adaptive Designs, etc.)</li> </ul>

<b>6 months in advance</b>	<ul style="list-style-type: none"> <li>Identify speakers and topic for each theme or broader topic (<i>it is recommended to have 3 talks per theme</i>)</li> </ul>
<b>5 months in advance</b>	<ul style="list-style-type: none"> <li>Send out announcements to Publications/Communication Officer (<i>Amstat News</i>), <i>Biopharmaceutical Report</i> Editor, and Webmaster</li> </ul>
<b>3 months in advance</b>	<ul style="list-style-type: none"> <li>Obtain abstract from speaker and set time/date with ASA Office</li> </ul>
<b>2 months in advance</b>	<ul style="list-style-type: none"> <li>Send out online registration to members</li> </ul>
<b>1 month in advance</b>	<ul style="list-style-type: none"> <li>Schedule a 20-min preparatory training for speaker in collaboration with ASA office</li> </ul>
<b>1 week in advance</b>	<ul style="list-style-type: none"> <li>Prepare introductory slides and upload speaker handouts to Biopharm Section website</li> </ul>
<b>On the day of training</b>	<ul style="list-style-type: none"> <li>Introduce speaker and facilitate the webinar</li> </ul>
<b>Within 3 weeks after webinar</b>	<ul style="list-style-type: none"> <li>Finalize payments coordinating with ASA Office</li> </ul>

### 3.5 Regulatory-Industry Statistics Workshop Committee

The co-chairs for the Regulatory-Industry Statistics Workshop consist of the Past President of the FDA Statistical Association and an industry appointee. The primary responsibility of the workshop co-chairs is to coordinate all activities related to the workshop and assemble a working committee to help with organizing activities. The term for the position is approximately 2 years. The co-chairs are appointed in Year 1 with responsibility for the Regulatory-Industry Statistics Workshop planning in Year 2.

#### 3.5.1 Committee and Chair Duties

- The co-chairs are responsible for coordinating the program. The budget, local arrangements, and the advertisements for this workshop are done in conjunction with ASA staff
- Co-chairs work with the ASA Conference Planner assigned to the Regulatory-Industry Statistics Workshop, the ASA Office, the Publications/Communication Officer, and others as necessary
- Attend EC meetings and provide update
- Ensure that the participants of the workshop follow BIOP's posted rules for workshop participation, available on the Workshop website.

The detailed activities of the committee are described in a separate document (Workshop Steering Committee Manual of Operations) that is maintained by the co-chairs and passed down to successors.

### 3.6 Contributed Paper Award Committee

The general responsibilities of the committee chair are to coordinate all activities related to the selection of the best contributed papers presented during JSM. The term of the committee chair is 3 years. Additional members may be appointed.

#### 3.6.1 Committee and Chair Duties

- Provide the Publications/Communication Officer a brief announcement regarding the Contributed Paper Award in time for publication in the June *Amstat News*
- Coordinate with the Program-Chair to identify and communicate to the ASA meetings office which presentations are eligible for the best contributed paper award. Eligible presentations are those in topic contributed or regular contributed sessions for which the Biopharmaceutical Section is the primary sponsor. Discussants and panelists are not eligible for the award, nor are presentations given in invited session
- Build communication strategy for this committee by working with Publication Officer and Communication Secretary. Communicate key events through appropriate communication channels through webmaster and Social Media Coordinator.
- Inform each session chair of the electronic voting process to be used at JSM, and request that they remind attendees of their session directly. If the session chair is deemed unlikely to inform the audience, arrange for an assistant to inform the session in place of or in addition to the session chair
- Maintain an analysis plan for processing of the data from the electronic voting process. The analysis plan should explicitly mention any requirements for a minimum number of votes needed for a presentation to be eligible for an award. A copy of the proposed analysis plan is attached as Appendix 2 in this document
- Based on the implementation of the analysis plan on the data from the electronic voting process, determine the highest-rated contributed paper. First and second runner-up awards and honorable mentions are also considered
- Provide winner information to the Treasurer by 31-MAY for ordering checks and certificates for the winner(s)
- Provide the Publications/Communication Officer a brief announcement regarding the Contributed Paper Award in time for publication in the September Issue of *Amstat News* so that authors can start thinking about presentations for the next year
- Attends the EC meetings and provides updates as necessary
- Attends JSM Mixer/Business meeting and presents awards
- Avoid conflict of interest: Chair and committee members should recuse himself/herself if there is a potential conflict of interest (co-author of the poster is his/her management or a subordinate). Chair and committee members should not participate in the poster award competition.

#### 3.6.2 Calendar of Activities

MONTH	ACTIVITY
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<b>JAN-FEB</b>	<ul style="list-style-type: none"> <li>Tally results from the previous year and determine winners based on separate analysis plan document</li> </ul>
<b>MAR</b>	<ul style="list-style-type: none"> <li>Recommend the number of winning papers and award amounts at the Spring EC meeting (e.g., 1<sup>st</sup> place \$1000, 2<sup>nd</sup> place \$600, 3<sup>rd</sup> place \$400, honorable mention(s) \$200)</li> <li>Only the first (presenting) author receives the award, but all authors receive a certificate; first author may request the monetary be split with co-authors</li> </ul>
<b>APR</b>	<ul style="list-style-type: none"> <li>Provide the Publications/Communication Officer a brief announcement about the Contributed Paper Award (e.g., awards will be presented at the upcoming JSM meeting and request that everyone please participate in the electronic voting process for any Biopharmaceutical Section contributed talks that they attend)</li> <li>Notify winners and obtain contact information (Organization and address for all winners); those winners who are subject to Federal US tax will be required to submit tax form provided by ASA</li> </ul>
<b>MAY</b>	<ul style="list-style-type: none"> <li>Provide Treasurer with winner information (name, address/phone, organization, title of presentation, wording for certificate, whether the awardee will attend the JSM BIOP Business Meeting / Mixer to receive award) for ordering certificates/monetary awards for winners by the ASA deadline no later than 31-MAY</li> </ul>
<b>JUN-AUG</b>	<ul style="list-style-type: none"> <li>Contact session chairs for upcoming JSM meeting and ask for their help in encouraging the audience to participate in the electronic voting process</li> <li>Attend the JSM meeting and remind each session chair prior to the session starting that the chair should encourage the attendees of the session to participate in the electronic voting process</li> <li>Present the awards to the winners from the previous year at the Biopharmaceutical Section Business Meeting (held in conjunction with the Mixer). Mail the awards after JSM to awardees who had intended to attend but did not</li> </ul>
<b>SEP-DEC</b>	<ul style="list-style-type: none"> <li>Submit an announcement about the award for the next JSM to the Publications/Communication Officer for <i>Amstat News</i> so that authors can keep the award in mind when submitting papers</li> </ul>

### 3.7 Contributed Poster Award Committee

The general responsibilities of the committee chair are to coordinate all activities related to the selection of the best contributed poster at JSM. The term of the committee chair is 3 years. Additional members may be appointed.

#### 3.7.1 Committee and Chair Duties

- Provide the Publications/Communication Officer a brief announcement regarding the Contributed Paper Award in time for publication in the June *Amstat News*

- Receive posters submitted for evaluation, review the posters, and determine the winners
- Provide winner information to the Treasurer by 31-MAY for ordering checks and certificates for the winner(s)
- Provide the Publications/Communication Officer a brief announcement regarding the Awards in time for publication in the September Issue of *Amstat News* so that authors can start thinking about presentations for next year
- Attends the EC meetings and provides updates as necessary
- Attends JSM Mixer/Business meeting and presents awards
- Avoid conflict of interest: Chair and committee members should recuse himself/herself if there is a potential conflict of interest (co-author of the poster is his/her management or a subordinate). Chair and committee members should not participate in the poster award competition.
- Build communication strategy for this committee by working with Publication Officer and Communication Secretary. Communicate key events through appropriate communication channels through webmaster and Social Media Coordinator.
- Assist the Chair-Elect with recruiting future committee members. Propose a committee member to be the Committee Chair for the next year.

### 3.7.2 Calendar of Activities

MONTH	ACTIVITY
<b>FEB</b>	<ul style="list-style-type: none"> <li>● Abstracts submitted online prior to JSM deadline</li> <li>● Determine deadlines necessary in order to make sure that names are submitted to ASA in a timely fashion</li> </ul>
<b>APR</b>	<ul style="list-style-type: none"> <li>● Ensure committee members are available to coordinate review efforts in a timely manner</li> </ul>
<b>MAY</b>	<ul style="list-style-type: none"> <li>● Contributor submits poster to the committee chair through email</li> <li>● Screen review (e.g., check appropriateness of topic, follows requirement, and classify the posters to several categories, etc.) and distribute the draft posters to reviewers for review along with a Poster Evaluation Form</li> <li>● Provide Treasurer with winner information from prior year (name, address/phone, organization, title of presentation, wording for certificate, whether the awardee will attend the JSM BIOP Business Meeting / Mixer to receive award) for ordering certificates/monetary awards for winners by the ASA deadline no later than 31-MAY</li> </ul>



<b>JUN-AUG</b>	<ul style="list-style-type: none"> <li>● Collect reviewer comments and decide the winners according to the reviewers' comments; hold a video/teleconference with committee members if necessary in the case of ambiguity regarding winners.</li> <li>● Recommend the number of winning papers and award amounts are as follows: 1<sup>st</sup> place \$1500, 2<sup>nd</sup> place \$800, 3<sup>rd</sup> place \$600, and honorable mention(s) \$300.</li> <li>● Place ribbons on the corner of the posters during the poster presentation at JSM to indicate the winners</li> <li>● Attend the JSM meeting</li> <li>● Present the awards (to the winners from the previous year at the Biopharmaceutical Section Business Meeting (held in conjunction with the Mixer). Mail the awards after JSM to awardees who had intended to attend but did not.</li> </ul>
<b>SEP</b>	<ul style="list-style-type: none"> <li>● Submit an announcement about the award for the next JSM to the Publications/Communication Officer for <i>Amstat News</i> so that authors can keep the award in mind when submitting papers</li> </ul>

### 3.8 Student Paper Award Committee

The general responsibilities of the committee chair are to coordinate all activities related to the selection of the student paper award. The term of the committee chair is 3 years. Additional members may be appointed.

#### 3.8.1 Committee and Chair Duties

- The committee chair will announce and advertise appropriately the Biopharmaceutical Section Student Paper Competition each year by communication to the various schools with graduate programs in statistics and announcements in whatever publications are appropriate. Announcements will be supplied in a timely manner so that the announcements appear with sufficient advance notice to meet JSM submission deadlines
  - Review all papers submitted to the Biopharmaceutical Section Student Paper Competition and select the winners of the competition.
  - Papers are submitted each year to the JSM Program Chair, who will ensure that submissions are adequately blinded, meet specified requirements, and are emailed to the committee chair
  - The chair will distribute the blinded papers and a standard score sheet to committee members for evaluation and scoring of each paper
  - A completed score sheet will be returned by each committee member to the committee chair according to the agreed timeline
  - Winner(s) selected based on scores
  - The committee chair will communicate to the JSM Program Chair the winning paper(s), and the Program Chair will then provide unblinded author information to the committee chair. If no paper is deemed worthy of an award, then it is acceptable for the committee to agree that no winner will be

selected

- The following cash prizes are approved but not required to be awarded: \$2000, \$1500, \$1000 and \$500 for 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and honorable mention, if needed. The prizes awarded will depend on the number and quality of papers submitted and the committee's decision. It would be possible, for example, to give a first prize and an honorable mention. The Chair of the student paper committee should annually evaluate the amount and number of prizes available and make recommendations for updates to the section Executive Committee.
- Maintain the rules for the competition. Periodically review those rules and recommend any proposed changes to the EC
- Provide winner information to the Treasurer by 31-MAY for ordering checks and certificates for the winner(s)
- Provide the Publications/Communication Officer a brief announcement regarding the Student Paper Award in time for publication in the September Issue of *Amstat News* so that authors can start thinking about presentations for next year
- Attends the EC meetings and provides updates as necessary
- Attends JSM Mixer/Business meeting and presents awards
- Avoid conflict of interest: Chair and committee members should recuse himself/herself if there is a potential conflict of interest (co-author of the poster is his/her management or a subordinate). Chair and committee members should not participate in the poster award competition.
- Build communication strategy for this committee by working with Publication Officer and Communication Secretary. Communicate key events through appropriate communication channels through webmaster and Social Media Coordinator.
- Assist the Chair-Elect with recruiting future committee members. Propose a committee member to be the Committee Chair for the next year.

### 3.8.2 Calendar of Activities

MONTH	ACTIVITY
SEPTEMBER	<ul style="list-style-type: none"><li>● Make announcement by September 30</li></ul>
OCTOBER and NOVEMBER	<ul style="list-style-type: none"><li>● Deadline for submission: Dec 1</li></ul>
DECEMBER	<ul style="list-style-type: none"><li>● Distribute blinded papers and score sheet to committee members for evaluation and scoring</li><li>● Review and winner selection: Dec 3rd to Jan 10th</li></ul>
JANUARY	<ul style="list-style-type: none"><li>● Finalize decision on winner(s) and liaise with Program Chair to obtain unblinded author information</li></ul>
MAY	<ul style="list-style-type: none"><li>● Provide Treasurer with winner information from current year (name, address/phone, organization, title of presentation, wording for certificate, whether the awardee will attend the JSM BIOP Business Meeting / Mixer to receive award) for ordering certificates/monetary awards for winners by the ASA deadline no later than 31-MAY. Mail the awards after JSM to awardees who had intended to attend but did not.</li></ul>
JUL-AUG	<ul style="list-style-type: none"><li>● Present the awards to the winners for the current year at the JSM Biopharmaceutical Section Business Meeting (held in conjunction with the Mixer).</li></ul>

### 3.9 Student Scholarship Award Committee

The general responsibilities of the committee are to coordinate all activities related to the selection of the student scholarships. The term of the committee is 3 years. The committee chair shall be the individual serving in their final year. Each year, one new member of the committee is appointed by the Chair-elect of the Biopharmaceutical Section and will participate starting in the fall of the year they were appointed.

The award will be based primarily on notable academic achievement or applied project work related to the area of biopharmaceutical statistics and will consider general academic performance, leadership, volunteering, and service. Annually, up to five students will each receive an award of \$3000. The Chair of the scholarship award committee should annually evaluate the amount and number of scholarships available, and make recommendations for updates to the section Executive Committee.

### 3.9.1 Committee and Chair Duties

- Ensures that the Biopharmaceutical Section Scholarship Award page on the Section website reflects the up-to-date student application and contact information for the committee chair (where applications will be sent)
- Receive applications from 01-JAN through 15-MAR
- Review applications to determine up to five winners to be announced mid-APR (or within ASA guidelines) to be included in the ASA Awards Program. Committee should ensure students meet the following criteria:
  - Applicants must have a Bachelor's degree and be enrolled in a Master's or Doctoral program in statistics or biostatistics
- Membership in the Biopharmaceutical Section is not required, however, ASA membership is a requirement
- Review application process yearly to determine if revisions are required
- Provide Treasurer with winner information (name, address/phone, organization, title of presentation, wording for certificate, whether the awardee will attend the JSM BIOP Business Meeting / Mixer to receive award) for ordering certificates/monetary awards for winners by the ASA deadline no later than 31-MAY
- Attends the EC meetings and provides updates as necessary
- Attends JSM Mixer/Business meeting and presents awards
- Build communication strategy for this committee by working with Publication Officer and Communication Secretary. Communicate key events through appropriate communication channels through webmaster and Social Media Coordinator.
- Assist the Chair-Elect with recruiting future committee members. Propose a committee member to be the Committee Chair for the next year.

### 3.10 ASA Fellows Nomination Committee

The responsibilities of the committee are to identify candidates who are members of the ASA Biopharmaceutical Section for ASA Fellows nomination. The term of the committee members is rotating for 3 years beginning on 01-MAR through end-FEB. The committee members must be BIOP ASA Fellows.

#### 3.10.1 Committee and Chair Duties

- Each year the committee will review the membership of the section to select potential Fellow nominees. The information on potential nominees should be maintained over time of potential candidates; the information should be maintained confidentially
- From the list of potential Fellow nominees, the committee will select those individuals to recommend as candidates
- The committee will work to identify and contact potential authors of Fellow nomination packages for the recommended subset of candidates. Other forms of support may also include any of the following, though none of these are requirements of the nomination committee:

- Authorship of a nomination package
- Assistance in writing or editing a nomination package
- Authorship of a supporting letter to be included in a nomination package
- The chair attends EC meetings and provides updates as necessary
- Attends JSM Mixer/Business meeting and presents list of newly elected BIOP Fellows
- Build communication strategy for this committee by working with Publication Officer and Communication Secretary. Communicate key events through appropriate communication channels through webmaster and Social Media Coordinator.
- Assist the Chair-Elect with recruiting future committee members. Propose a committee member to be the Committee Chair for the next year.

### 3.10.2 Calendar of Activities

MONTH	ACTIVITY
<b>MAR-JUL</b>	<ul style="list-style-type: none"> <li>● Review and update candidates for ASA Fellow nomination</li> <li>● Contact candidates to: <ul style="list-style-type: none"> <li>○ Determine their interest in the ASA Fellow award, and their willingness to support efforts on their behalf to obtain the award</li> <li>○ Obtain a current copy of their curriculum vitae</li> </ul> </li> </ul>
	<ul style="list-style-type: none"> <li>○ Obtain names of several individuals who are well acquainted with their professional career and who might be willing to prepare a Fellow nomination package</li> <li>● Select tentative subset of candidates to recommend for Section support of Fellow nomination packages</li> </ul>
<b>JUL-AUG</b>	<ul style="list-style-type: none"> <li>● Report on successfully elected new Fellows at the Biopharmaceutical Section Business Meeting (held in conjunction with the Mixer)</li> <li>● Remove candidates who received ASA Fellow award at JSM from list of Fellow candidates</li> <li>● Finalize subset of candidates to recommend for Section support of Fellow nomination packages</li> <li>● Identify potential authors of nomination packages for subset of candidates selected</li> </ul>
<b>SEP</b>	<ul style="list-style-type: none"> <li>● The Chair will inform Biopharmaceutical Section Executive Committee of subset of candidates recommended for Section support of ASA Fellow nomination packages</li> <li>● For candidates supported by Executive Committee, Committee members will contact potential authors of nomination packages to express the interest of Biopharmaceutical Section in seeing that Fellow nomination packages are submitted, and to see if potential authors are willing to author a nomination package, or would know other ASA members who might be willing to do so</li> </ul>
<b>SEP-FEB</b>	<ul style="list-style-type: none"> <li>● Submit letters or nomination package(s), as appropriate, in a timely manner</li> <li>● Assist candidates as requested</li> </ul>

### 3.11 Membership Committee

The general responsibilities of the committee are to assess the demographics and interests of the membership. The term of the committee chair is 3 years. At least one additional committee member will be appointed.

#### 3.11.1 Committee and Chair Duties

- Assess the demographics and interests of the Section in various activities by means of administering a current member survey. Conduct a new membership survey every 3 years and report results to the EC. The results of the next survey are due in 2021. The membership Committee and EC members must be excluded from any incentives/prizes given out to encourage survey participation.
- Recommend strategies that will keep current members actively involved in the section activities and assist BIOP EC in implementing them
- Evaluate and implement methods for increasing the ASA Biopharmaceutical membership in underrepresented demographics (e.g., students, international statisticians; liaising with other professional statistical societies)
- Liaise with ASA regarding any association-wide membership efforts. Bring back any issues for discussion to the BIOP EC
- Attend EC meeting and provide update
- Attends JSM Mixer/Business meeting, manages sign-in for the mixer, and collects attendance for the JSM Mixer/Business meeting
- Assist the Chair-Elect with recruiting future committee members. Propose a committee member to be the Committee Chair for the next year.

#### 3.11.2 Calendar of Activities

MONTH	ACTIVITY FOR SURVEY
JAN	<ul style="list-style-type: none"><li>● Define objectives for the current year</li></ul>
FEB	<ul style="list-style-type: none"><li>● Review the previous survey and prepare the new survey and the strategy for the administration and advertisement</li></ul>
MAR	<ul style="list-style-type: none"><li>● Submit to EC and receive approval of the proposed survey</li></ul>
MAY	<ul style="list-style-type: none"><li>● Advertise survey to members</li></ul>
JUN	<ul style="list-style-type: none"><li>● Enter the survey in SurveyMonkey.com</li></ul>
JUL-AUG	<ul style="list-style-type: none"><li>● Conduct online survey (time period to cover JSM)</li><li>● Analyze survey responses</li></ul>
SEP	<ul style="list-style-type: none"><li>● Draft summary of survey results for review at Transition meeting</li></ul>
NOV-DEC	<ul style="list-style-type: none"><li>● Provide final survey results for publication in the next Biopharmaceutical Report</li></ul>

### 3.12 Mentoring Committee

The responsibilities of the committee are to manage the mentorship activities within the section. The term of the committee chair is 3 years. Additional members of the committee may be added.

#### 3.12.1 Committee and Chair Duties

- Each year the committee will match mentors with mentees and provide guidance for the mentorship program
- The chair attends EC meetings and provides update as necessary
- Attends JSM Mixer/Business meeting and assists with the sign-in process
- Assist the Chair-Elect with recruiting future committee members. Propose a committee member to be the Committee Chair for the next year.

### 3.13 Outreach and Collaboration Committee

The goal of the Outreach and Collaboration Committee (OCC) within ASA BIOP section is to engage with other biopharmaceutical statistics professional societies and other ASA Chapters, Sections, and Interest Groups with synergistic objectives and interest. The associations with different societies can vary depending on the overlaps, geographical proximities, and mutual interests. These may include, but not limited to, conducting relevant mutually beneficial information exchange, and explore opportunities to coordinate and collaborate in scientific research that would benefit the membership of BIOP, other global societies and the biopharmaceutical statistics profession at-large. The term of the committee chair is 3 years. Additional members of the committee may be added.

The formation of this team is to consolidate and make consistent the efforts of the following committees where were previously available in the Biopharmaceutical Section:

- Cross-Section and Chapter Committee
- Other Organizations Committee
- International Statisticians Committee

To sustain the theme of collaboration and outreach, BIOP needs to focus on both strategic partners and opportunistic partners in the profession. Strategic partnership needs thorough thinking about the need and benefit of partnering with certain societies with maximum potential benefit to the BIOP members through the knowledge exchange. Opportunistic partnership focuses on having the right mindset in accepting others as a one-off collaboration.

#### 3.13.1 Committee and Chair Duties

- The chair attends EC meetings and provides updates of ongoing and completed activities, future possibilities and seek approval for any activities that may need funding
- Coordinate knowledge-sharing with ASA sections, chapters and associated

organizations ( e.g., IISA, ICSA, etc.)

- Appoint a liaison officer for ASA who will be responsible for exploring activities of relevant ASA committees (CAS, Leadership Council, CoSGB, etc.) to bring relevant ASA initiatives to BIOP members
- The liaison officer will also be the POC (Point of Contact) for ASA and other sections in exploring and supporting inter-section collaboration
- Participate in ASA's student focused initiatives (K-12, College) to include statistical applications and knowledge relevant to biopharmaceutical research. Identify and appoint appropriate volunteers from BIOP to help in this regard, including finding speakers for speaker series, material to include in presentations, etc.
- International outreach
- Appoint a liaison officer for EU and Asian associations and evaluate opportunities
- Assist the Chair-Elect with recruiting future committee members. Propose a committee member to be the Committee Chair for the next year.

### 3.14 Next Generation Stewardship Committee

The Next Generation Stewardship Committee exists to promote active and responsible stewardship of BIOP monetary resources in service to Section membership and the profession. The Committee shall consist of at least 3 members (including Committee Chair and Committee Past Chair) and no more than 5 members. As the committee's first official year was 2021, the first new member(s) are to be appointed by the Section Chair-elect, with first appointments to have term(s) beginning in 2024, unless there are resignations needing replacement appointments prior to 2024.

#### 3.14.1 Committee and Chair Duties

- Meetings of the committee shall be called, as needed, by the Chair. At least two meetings per year of the committee shall occur. The current chair of the Section's funding committee shall be a nonmember standing invitee to committee meetings to facilitate open communication between the two committees.
- Committee convenes informational meetings and correspondence with members of the Section, its working groups, interest groups, or committees in furtherance of its mission.
- Committee brings forth spending proposals for Executive Committee vote and execution.
- Committee documents such spending approvals in Google Doc for future reference.
- Assist the Chair-Elect with recruiting future committee members. Propose a committee member to be the Committee Chair for the next year.

#### 3.14.2 Committee Duration and Governance

- The tenure of the Committee is initially for 5 years, beginning in 2021. The



Committee will continue beyond the year 2025, according to vote of the Executive Committee of the Section.

- The first vote for renewal of the Committee may occur in 2025, allowing extension of the Committee in 2026 and beyond, as determined by the Executive Committee.

### 3.15 Leadership-in-Practice Committee

The role of the Leadership-in-Practice Committee is to enable and bolster opportunities for the development of practical leadership skills among statisticians working in biopharmaceutical jobs. A key goal of the committee is to bring leadership training from a conceptual to a “practical” level by incorporating examples of how skills are applied to everyday job situations as often as possible and providing tips that are “ready to apply” in a job or other professional setting.

#### 3.15.1 Committee and Chair Duties

- Assist in the advancement of knowledge in leadership development skill and techniques contributing to the field of statistics
- Establish and maintain liaison and cooperation with other professional leadership development organizations or entities
- Plan, organize or support appropriate sessions on leadership development training or discourse at JSM, as well as other ASA and BIOP forums
- Establish and maintain liaison with other Sections within ASA
- Contribute, in appropriate ways, to shaping the discourse across ASA on the evolving expectations around leadership, influence and impact of statisticians
- Assist, as feasible, in the development of curricula and leadership training programs and workshops for statisticians.
- Provide updates to Biopharmaceutical Section Executive Committee.

### 3.16 Scientific Working Group Proposal Committee

The role of the Scientific Working Group Proposal Committee is to assess proposals from BIOP section members to start new scientific working groups. The committee has two co-chairs who serve terms of 3 years. Additionally, 2 to 3 members may be added.

The ASA Biopharmaceutical Section recognizes the value of cross-community efforts in advancing statistical and regulatory science. To enable this, the executive committee encourages members to submit research topics that contribute to the goals of advancing the science, enabling innovation, and leveraging the expertise of the broad membership affiliations of the section. BIOP members are encouraged to submit proposals to the Scientific Working Group Proposal Committee for review and if appropriate, subsequent consideration by the section executive committee. The proposal should follow the [template](#), so that, if acceptable, it can be used as the basis of a scientific working group charter.

#### 3.16.1 Committee and Chair Duties

- Assess the proposals for completeness, innovation, and value-added potential for the section; Co-chairs do the initial assessment and contact individuals submitting proposal for additional information as necessary and provide the proposal to the committee members when ready
- Hold meetings to evaluate new proposal; proposals should be sent through the dedicated email address for proposals
- Once proposal has been considered complete, the committee will work with the members requesting to form a group to ensure package of information put together for EC review is of high quality
- The co-chairs notify the individuals who submitted the proposal on the acceptance or decline by the EC
- The co-chairs attend EC meetings and provides update as necessary
- Send out yearly health-check to chairs of SWGs in November to determine if SWGs are meeting the goals stated in their charters. Otherwise, the SWG committee may recommend to the EC that a SWG should be disbanded at the Spring EC Meeting.
- Assist the Chair-Elect with recruiting future committee members. Propose a committee member to be the Committee Chair for the next year

### 3.17 Nonclinical Biostatistics Working Group

The Nonclinical Biostatistics Working Group (NCBWG) is a unique working group within BIOP whose responsibility is the organization and management of the NCB conference. At its discretion, the NCBWG may also have other work streams if it so desires, however, these are not separate working groups. The NCB conference chair and the NCBWG chair have non-voting seats within BIOP.

#### 3.17.1 Committee and Chair Duties

- The NCBWG and NCB conference chairs attend the EC meetings and provide updates as necessary
- The NCBWG is responsible for choosing the working group and NCB conference chairs
- The NCBWG is responsible for a process of working with the BIOP Treasurer to create a NCBWG budget, and then approving the budget so the BIOP Treasurer can submit the budget to ASA by end of October.

### 3.18 SurveyMonkey (aka Momentive) Manager

The SurveyMonkey manager is responsible for maintaining SurveyMonkey for the use of the BIOP Section members. This includes ensuring all fees are paid and the password is maintained in a secure manner. The section Secretary acts as the back-up for the Survey Monkey manager.

The SurveyMonkey Manager is an appointed position with no defined duration.

### 3.19 **Social Media Coordinator**

The primary responsibility of the Social Media Coordinator is to communicate the Biopharmaceutical Section events and announcements through social media. The Social Media Coordinator is appointed for a 3-year term by the section Chair-Elect.

#### 3.19.1 **Social Media Coordinator Duties:**

- Create/maintain social media accounts, including Twitter, LinkedIn, and YouTube accounts
- Converts Section-generated documents for social media postings including all appropriate links
- Stay up to date on the communication calendar and ensure timely social media posting
- May develop materials to promote the awareness of Biopharmaceutical Section and Biopharmaceutical statistics knowledge (mostly in partnership with other sub-committees)
- Attends EC meetings and provides updates

### 3.20 **Communication Secretary**

The primary responsibility of the Communication Secretary is to create and maintain the communication calendars and remind sub-committees to provide necessary communication information on time. The Communication Secretary is appointed for a 3-year term by the section Chair-Elect.

#### 3.20.1 **Communication Secretary Duties:**

- Create and maintain the communication calendars under the guidance of Publications/Communication Officer
- Remind and follow up with sub-committees for communication information
- Follow up with each communication channels to make sure the communication occurs on time.
- Attends EC meetings and provides updates

## APPENDIX A

### Template for proposal to form a new BIOP Committee

#### Section 1. Background

Include a brief description of the rationale and mission for the formation of such a committee.

#### Section 2. Objectives and Deliverables

Include a brief description of objectives and expected deliverables and/or benefit to the BIOP members.

#### Section 3. Structure

Include a brief description of

- Membership
- Roles and responsibilities
- Committee structures
- Any information repository, if relevant
- Duration of such a committee, as relevant

## APPENDIX B

### **ASA Biopharm (BIOP) Conference Funding Request Information Form**

The ASA Biopharmaceutical Section (BIOP) does consider requests for conference supports where the Section or its members derive benefit in accordance with its mission. The BIOP Executive Committee (EC) reviews and votes on all funding requests during one of its scheduled meetings. Grants are generally given one time only. If funds are granted, recipient organizations are expected to submit a report to BIOP EC on final conference participation level of BIOP registrants, benefits, and speakers.

Name of Conference:

URL:

Dates:

Location:

Year Began, # previous meetings:

Requestor Name and Phone/Email:

Amount requested:

Reasons for the funding and justifications of the benefit to BIOP members, and why conference and/or membership dues cannot cover the event:

Previous Requests for BIOP Funding (year, result, and amount funded):

Registration Fee:

Other sources of funding received or being sought:

=====

Attendance History: Please provide total and BIOP member attendance (%) for the last 3 meetings:

Expected Attendance this year and basis for estimate:

Speaker Composition:

- # of total talks =
- # of BIOP member speakers =
- # invited sessions =
- # invited BIOP member speakers =

Planned BIOP-Related Session Titles or Talks:

If BIOP supports, what direct benefits would BIOP members receive?

If BIOP supports, what indirect benefits would BIOP members receive?

How would BIOP support be acknowledged for the conference?

### **ASA Biopharm (BIOP) Conference Funding Report Form**

When ASA Biopharmaceutical Section (BIOP) funds are granted, recipient organizations must submit the below report to the BIOP Executive Committee no later than 4 weeks after the conference on final conference participation level of BIOP registrants, benefits, and speakers. Please submit report to the BIOP Chair.

Name of Conference:

Dates:

Location:

Requestor Name and Phone/Email:

Amount received:

Registration Fee:

Registration Fee for BIOP members:

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**Attendance this Year**

- # of participants =
- # of participants that were BIOP members =

**Final Speaker Composition**

- # of total talks =
- # of BIOP member speakers =
- # invited sessions =
- # invited BIOP member speakers =

**List BIOP-Related Session Titles or Talks:**

- 

**List Direct/Indirect Benefits to BIOP Members/Section (Please provide specific examples):**

- 

**Describe How BIOP Support was Acknowledged During the Meeting/Conference:**

**Describe How BIOP Funding Helped with Having a Successful Meeting (Please provide specific examples:**