

**PROGRAM DESCRIPTION**

**OFFICE OF TRANSLATIONAL SCIENCES**

**OFFICE OF BIOSTATISTICS**

**STATISTICAL POLICY COUNCIL**

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**PURPOSE**

This MAPP describes the organization, membership, responsibilities, and procedures of the Statistical Policy Council (SPC) in the Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER). This MAPP serves as the charter for the SPC. The MAPP also describes the organization, membership, responsibilities, and procedures of working groups and committees that have been established through the SPC. The MAPP is being revised to update the SPC’s organization, responsibilities, and procedures.

**BACKGROUND**

The SPC provides senior leadership to CDER on statistical policy development, dissemination, and implementation, including:

- Attention to and management of essential cross-cutting statistical policy
- Advocacy for the consistent and transparent application of statistical policy

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throughout CDER

- Promotion and coordination of communication both internally and externally on statistical policy decisions made by the SPC

The SPC provides a senior-level forum to establish statistical policy for CDER and oversee its application in both pre- and postmarket review activities and related programs. The goals of the SPC are: (i) to ensure the conduct of high-quality statistical reviews based on sound statistical methodologies and the best available statistical practice in evaluating studies and submissions in CDER; and (ii) to promote consistency of statistical reviews across biometrics divisions and across medical divisions and offices within CDER.

Statistical issues may arise for which there is no established policy or procedure. Such statistical issues can relate to study design, study conduct, data handling, data analysis, and interpretation of study results. While some variation in the application of statistical methods across disease areas is expected and desired, the consistent application of sound statistical principles throughout CDER is essential to OB's mission and reflects the need for clarity and consistency of reviews.

CDER is occasionally challenged on its perceived statistical standards, the manner in which statistical decisions are reached, or the variation in the acceptance of statistical methods across medical divisions. Having a committee to establish statistical policy and guide reviewers in the application of these policies can help address these challenges.

The SPC meets on a regular basis to consider statistical policy issues that are complex or precedent setting and require input from senior management in OB. Although the issues discussed by the SPC may have been triggered by a specific statistical review, the policy established by the SPC is applied to all reviews for which the policy is relevant.

For the purposes of the SPC, statistical policy generally concerns one or more of the following: clinical study/trial design; statistical analysis planning and execution; analysis data quality and/or standards; interpretation of results to establish favorable benefit-risk; data/trial monitoring for safety and/or effectiveness; postmarketing safety assessments; evaluation and qualification of biomarkers, clinical outcome assessments, other related measurement methods and technology, and their derived endpoints; and statistical support of nonclinical assessments (e.g., carcinogenicity, chemical, manufacturing, and control processes, etc.).

To be considered by the SPC, a statistical policy issue typically would meet one or more of the following criteria:

- A novel trial/study design
- A novel approach to address a statistical methodological issue
- A statistical policy issue on which OB seems to have taken inconsistent positions over time or across therapeutic areas

- Strategies for implementation of a new statistical policy
- Strategies for effective communication of new or existing statistical policies

This MAPP describes the organization, membership, responsibilities, and procedures for the SPC in OB.

## RESPONSIBILITIES

### The SPC:

1. Develops, establishes, and recommends CDER statistical policies and procedures that pertain to study design and conduct, data handling, statistical analysis, and interpretation of study results.
2. Provides input to the development and review of CDER policy documents generated outside OB. These documents often raise important statistical policy issues or impact existing statistical policies and procedures. The SPC ensures that these documents are consistent and reflect good statistical practices.
3. Identifies crucial or emerging statistical issues and areas that lack appropriate statistical methodologies and study designs.
4. Determines when a policy issue, identified by the SPC or proposed for SPC consideration by a reviewer, merits formation of a working group or committee. When identified, the SPC develops a clear and concise charge to the working group or committee. This includes outlining the issues to be addressed by the group and identifying expected deliverables and an anticipated timeline.
5. Reviews and evaluates the deliverables of working groups or committees in a timely fashion.
6. Determines whether any policy document produced by a working group is recommended for approval and adoption as statistical policy for OB; additionally, determines whether the policy document should be considered for further development as a CDER clinical or statistical guidance document.
7. Determines whether to approve any recommendation about a review practice made by a working group in a form other than through development of a policy document. If approved and adopted, determines whether a new standard operating procedure is needed or an existing standard operating procedure should be modified.
8. Develops or reviews a dissemination and training plan for each policy decision or document approved and adopted by the SPC; determines the scope of such plans for training reviewers outside OB.
9. Reviews the OB research and statistical/regulatory training programs.
10. Provides input on specific review program issues (e.g., about approvability or

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labeling issues or how to frame conclusions and recommendations) that may benefit from senior management discussion or direction.

**OB Director:**

1. Appoints the Chair of the SPC
2. Consults with the Chair to appoint a Project Manager
3. Serves as a permanent member of the SPC
4. Selects up to four at-large members of the SPC, including clinicians, as needed
5. Invites (or delegates to the Chair to invite) subject matter experts or other relevant attendees to the SPC meetings depending on the item(s) under discussion
6. Works with the SPC Chair to appoint chairs for working groups and standing committees

**OB Deputy Director, Immediate Office Associate Directors, Division Directors:**

1. Serve as permanent members of the SPC

**The Person(s) Bringing Issues to the SPC:**

1. Submits requests for discussion topics to the Project Manager for consideration by the Chair. Identifies any time sensitivity in scheduling so that every effort can be made to meet such needs.
2. Submits a list of recommended attendees to the Project Manager to facilitate productive discussion of the topics.
3. Submits meeting background material.
  - a. Material should ideally be provided at least 5 business days in advance of the meeting. A minimum of 2 business days is required, but the shorter time frame may reduce the quality of the discussion.
  - b. Background documents should leverage any already produced material to minimize production of new material.
  - c. Background material should include specific questions for the SPC to provide input and/or vote on.
  - d. Background material should be concise (e.g., a summary document for a review program issue should ideally be no longer than five pages).
4. Introduces the topic and questions for discussion at the SPC meeting. The length of all presentations should be kept to a minimum (ideally no longer than 10 minutes) to allow for maximum time for discussion of the questions.

**OB Division Directors:**

1. May appoint a member from their own division to each working group and standing committee

**Working Groups:**

1. Maintain a charter describing key objectives, roles and responsibilities, deliverables, and timelines.
2. Seek further clarification from the SPC, if needed, to ensure the working group's charge is well understood by all group members.
3. Identify the information and expertise needed to perform the charge of the working group and seek input and additional expertise, as needed, to carry out the charge.
4. Evaluate existing approaches to the statistical problem or review practice under consideration.
5. Determine whether new statistical methodologies are needed. If so, oversee the development of those methodologies.
6. Develop and return to the SPC a recommendation or policy document to adequately and appropriately address the charge of the working group.

**Committees:**

1. Maintain a charter describing key objectives and roles and responsibilities.
2. Ensure the committee's charge is understood by all members. If necessary, seek further clarification from the SPC.
3. Identify the information and expertise needed to perform the charge of the committee. Seek input and additional expertise, as needed, to carry out the charge.
4. Carry out the work of the committee. Periodically evaluate whether the original charge is still appropriate or needs modification. Advise the SPC of any changes needed.

**PROCEDURES**

**SPC:**

1. SPC meetings will be held monthly or twice monthly, or as needed.
2. All SPC members attending an SPC meeting are expected to have reviewed and considered any background material prior to the meeting.

3. All SPC members attending an SPC meeting are expected to provide input or a vote (if a decision is requested) on the issue(s) or question(s) at hand. If a decision is requested, decisions will be established through deliberation among all SPC members attending an SPC meeting, reaching resolution through consensus, or through majority voting, if consensus cannot be reached.

**SPC Chair:**

1. Presides over SPC meetings, prepares meeting agendas, issues meeting minutes, and sets the priorities for the SPC's activities.
2. Appoints chairs for any working groups and committees that the SPC determines are needed.
3. Ensures policy recommendations and documents produced by working groups or committees are reviewed, discussed, evaluated, and voted upon (if applicable). Ensures decisions are taken and can be acted on in a timely fashion following completion of the working group's or committee's charge.
4. Ensures the dissemination and training plans developed by the SPC are carried out. These may relate to new policies and procedures or changes in existing ones.
5. Provides periodic reports to the OB Director on the recommendations, actions, and positions taken by the SPC.
6. Presents or delegates to other(s) to present new policy decisions to relevant bodies outside OB, such as CDER's Medical Policy Council, and leads or delegates to other(s) to lead discussions about the implications of statistical policy changes.

**SPC Project Manager:**

1. Serves as a point of contact for communication to and from the SPC.
2. Schedules meetings and communicates the agenda and any background material prior to each meeting.
3. Prepares minutes that record all decisions, actions, and recommendations by the SPC. Minutes should be made available by 1 week after an SPC meeting.
4. Maintains records of background materials and documentation of SPC decisions, actions, and recommendations. Maintains a repository of those records that is available to OB.

**Working Group and Committee Chairs:**

1. Preside over working group and committee meetings. Schedule meetings and prepare agendas and minutes of the meetings, or assign a designee to do so.

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2. Provide periodic reports to the SPC on progress of the working group or committee. Include documentation of any activities undertaken during the reporting period, as well as challenges or issues encountered.
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## DEFINITIONS

**Working Group:** A group of individuals assigned a specific task with a defined deliverable and completion date. A working group will have a limited life span. The working group will adjourn when it has successfully completed its goal or additional work is not required as determined by the SPC.

**Committee:** A standing committee established to address a policy issue that requires continual assessment or to serve an ongoing policy-related function for the Office. Examples include a Publications Committee and a Training Committee. A committee will have an extended life span. A committee will be disbanded either when it has successfully completed its goal, or its purpose no longer meets the goals of the SPC.

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## AUTHORITY

The SPC will have the authority to:

- Establish and disseminate statistical policy
  - Establish and disband committees
  - Establish and abolish working groups
  - Provide direction and feedback to committees and working groups
  - Ratify committee and working group recommendations
  - Provide input to review teams on specific review program issues
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## ORGANIZATION

### SPC:

1. Chair: The Director of the Office of Biostatistics will appoint the Chair.
2. Project Manager: The Office Director in consultation with the SPC Chair will appoint a Project Manager.
3. Members: Permanent members of the SPC will include:
  - a. Director of the Office of Biostatistics
  - b. Deputy Director of the Office
  - c. Associate Directors of the Office
  - d. Division Directors within the Office

- e. At-large members: The Office Director may select up to four at-large members to serve on a rotating basis.
4. Other Attendees: Other OB supervisors and Associate Directors are expected to attend SPC meetings but are not permanent members of the SPC.
5. Other Invitees: The Office Director and/or Chair may invite other experts to attend one or more meetings of the SPC, if the discussion of a particular topic will be enhanced by their input.

**Working Groups:**

1. Chair: The SPC Chair in consultation with the Office Director will select a chair for each working group.
2. Members: The Director of each biometrics division will have the opportunity to appoint a member to each working group but may decline. Topics for which the SPC determines that office-wide input is important should have representation from all divisions. The Office Director may appoint a working group member(s) from among the Deputy Director, Associate Directors, and staff in the Immediate Office. The working group chair may select additional members, taking into account their expertise and interest in the topic. In general, working group membership should not exceed 10-12 members plus the chair.

**Committees:**

1. Chair: The SPC Chair in consultation with the Office Director will select a chair for each committee.
  2. Members: Committees are expected to have representation from each biometrics division. The Division Directors will appoint a member from their respective division to serve on the committee. The Office Director may appoint a working group member(s) from among the Deputy Director, Associate Directors, and staff in the Immediate Office. The committee chair may select additional members, taking into account their expertise and interest in the topic. In general, committee membership should not exceed 10-12 members plus the chair.
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**SUMMARY OF CHANGES**

The Statistical Policy Coordinating Committee was established in 1999. The name of this committee was changed to the Statistical Policy Council (SPC) in 2016. This MAPP provides an update to the 2016 MAPP to reflect changes in the SPC's organization, responsibilities, and procedures.

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**EFFECTIVE DATE**

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This MAPP is effective upon date of publication.

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**CHANGE CONTROL TABLE**

<b>Effective Date</b>	<b>Revision Number</b>	<b>Revisions</b>
7/22/99	Initial	n/a
3/9/16	1	Committee renamed. MAPP updated to reflect current working practices.
5/24/21	2	MAPP updated to reflect changes in the SPC's organization, responsibilities, and procedures.