
POLICY AND PROCEDURES

**OFFICE OF TRANSLATIONAL SCIENCES
OFFICE OF BIOSTATISTICS**

Policy and Procedures for Creating an Interest Group in the Office of Biostatistics

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PURPOSE

This MAPP outlines the process and requirements for creating an interest group (IG) in the Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER).

BACKGROUND

An IG is a group of OB staff members with a common interest in a particular topic. The topic can be scientific, social, or procedural. Examples of IG activities may include, but are not limited to, journal clubs, hands-on training experiences, lectures and seminars, and improvements to processes or tools used by the Office. In OB, an IG is distinct from a working group or committee. OB working groups and committees are created by the OB Statistical Policy Council (SPC), with associated policies and procedures described in MAPP 6610.1 *Statistical Policy Council*. The views and recommendations expressed by IGs do not necessarily reflect OB policies or procedures on a particular topic.

POLICY

IGs are initiated and managed by individuals within OB. IGs can include members outside of OB with approval from their supervisors. OB encourages the formation of IGs to do the following:

- Support professional development based on scientific interests

- Develop increased scientific expertise within OB
- Provide opportunities for professional mentorship within OB
- Provide opportunities to work with fellow OB members for the betterment of OB

PROCEDURES

To create an IG, an individual or a group of individuals should do the following:

1. Prepare a one-to-two-page proposal requesting to create the IG that includes: the rationale, goals and/or deliverables, planned duration of the IG (which may depend on the deliverables), and a list of the intended initial IG members.
2. Obtain approval for participation of all individuals in the IG from their immediate supervisors or Division Directors(following division procedures).
3. Obtain approval for creation of the IG from the appropriate manager. If the IG is within a division, approval should be obtained from the OB Division Director. For within-division IGs focused on topics that are broadly relevant to the office and/or may overlap with ongoing OB working group or committee efforts, the Division Director should discuss with office leadership prior to approval. If the IG is across divisions within OB, approval should be obtained from the OB Office Director, or a designee. A presentation of the proposal to Division or Office leadership may be requested. Proposals with a purpose linked to OB strategic plan initiatives are more likely to get approved.

Other operational procedures include the following:

1. The Division or Office Director may assign an OB member, or a group of OB members (e.g., a steering committee), to oversee or consult with the IG.
2. Each IG should decide on organizational structure (e.g., any sub-teams), term duration for committee members (this may not always apply), leads or points of contact, and any additional positions. Rotation of committee members and/or responsibilities is encouraged.
3. The maximum amount of official work hours per pay period that an OB member can use to work on IG projects is determined by the member's supervisor and/or Division Director. Continued participation in IG activities is dependent on the member getting other assigned work completed.
4. The approved IGs should maintain a wiki page within the OB Wiki. This wiki page should include the proposal, list of members, organizational structure, activities, and any outcomes and progress of the IG. The IG should assign the responsibility of maintaining the IG wiki page to a member or members.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
6/23/22	Int.	New MAPP