POLICY AND PROCEDURES

OFFICE OF CLINICAL PHARMACOLOGY

Scientific Interest Groups: Criteria and Policies

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PURPOSE

- This MAPP outlines the process and requirements for creating a Scientific Interest Group (SIG) in the Office of Clinical Pharmacology (OCP) in the Center for Drug Evaluation and Research (CDER).

BACKGROUND

- A SIG is a group of volunteer members with a common interest in a particular scientific topic. The SIG will be initiated and managed by individuals within OCP. A SIG is to be distinguished from a working group. Examples of SIG activities may include, but are not limited to, journal clubs, hands-on training experiences, cross-specialty trainings, lectures and seminars, and development and discussion of better science and tools used by the Office.

POLICY

OCP encourages the formation of SIGs as a means to:

- Support professional development based on personal scientific interests
- Develop increased scientific expertise within OCP
- Provide opportunities for mentorship within OCP

PROCEDURES

To create a SIG, a qualified individual or group of individuals should:

1. Generate the initial idea for the creation of a SIG, prepare a one-to-two page synopsis indicating the rationale, goals, and interests of the intended SIG membership, and secure approval from immediate supervisors (i.e., the division director or deputy director).

2. Recruit a preliminary steering committee for the SIG through e-mail, telephone, or verbal discussions to secure at least three individuals who concur with the idea. These individuals must also secure approval from their immediate supervisors. These individuals will serve as the Acting Steering Committee until approval of the SIG.

3. Finalize the proposal for the SIG with a brief description (less than two pages) of the proposed SIG, including its purpose, specific objectives, and the number of members recruited to date. The SIG proposal should be presented for approval to the Senior Leadership Team (SLT) by a member of the Acting Steering Committee. The probability of a SIG being approved will be highest when the purpose is linked with OCP strategic plan initiatives. Please refer to OCP intranet sites for the current OCP strategic plan initiatives.

Other operational procedures include the following:

1. Each SIG will self-govern, decide on organizational structure, including size of the steering committee, term duration for committee members, leads or points of contact, and any additional positions. Rotation of committee members is encouraged.

2. OCP staff can use up to four official work hours per week to work on SIG projects as staff development. Continuing participation in SIG activities is dependent on the member getting his or her Office work completed, as determined by the member's supervisors.

3. The approved SIGs, their meeting minutes, and the activities and outcomes of approved SIGs will be posted on the OCP intranet site. These tasks will be the responsibility of the Steering Committee.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
09/01/21	1	• Added clarity on the steering committee's role • Removed reference to defunct intranet link • Added clarity on OCP staff involvement in SIGs