OFFICE OF CLINICAL PHARMACOLOGY

Scientific Interest Groups: Criteria and Policies

CONTENTS

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 experience, cross-specialty training, recommendations for forming working groups for guidance or MAPP development, lectures and seminars, and development and discussion of better science and tools used by the office.

POLICY

The OCP encourages the formation of SIGs as a means to:

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

PROCEDURE

- **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 1-2 page synopsis indicating rationale, goals, and interests of the intended SIG membership, and secure approval from the immediate supervisors (i.e., the division director or deputy director).

(2) Recruit members 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. The original three individuals will serve as the Acting Steering Committee until approval of the SIG.

(3) Finalize the proposal for the SIG with a brief description (< 2 pages) of the proposed SIG, including its purpose, specific objectives, and the number of members recruited to date. The SIG proposal will need to be presented to the Senior Leadership Team (SLT) by a member of the Acting Steering Committee for approval. The probability of a SIG being approved will be highest when the purpose is linked with OCP strategic plan initiatives (http://intranetappslb.fda.gov/scripts/OCP_Apps/strategic_plan/).

- **Other operational procedures include the following:**

(1) Each SIG will have a minimum of three members. The SIG members will elect a Chairperson and the Steering Committee. Once the SIG is established, each SIG will self-govern, decide on organizational structure, including number/size of Steering Committee, term duration for committee members and chair, and any additional positions. Rotation of committee members is encouraged.

(2) Additional members may join the SIG at any time, but must have their supervisor's concurrence. 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) SIG members can use up to 4 official work hours per week to work on SIG projects as staff development. Involvement in more than one SIG group would depend on discussion with supervisors.

(4) The approved SIGs, meeting minutes, and the activities and outcomes of approved SIGs will be posted in the OCP eRoom. This will be the responsibility of the Steering Committee.

EFFECTIVE DATE

This MAPP is effective upon date of publication.