# PHARMACOLOGY AND TOXICOLOGY

## Management of CDER Pharmacology/Toxicology Coordinating Committee

**CONTENTS**



## PURPOSE

- This MAPP describes:
  - The role and responsibilities of the Pharmacology/Toxicology Coordinating Committee (PTCC).
  - The procedures to be used for establishing pharmacology/toxicology subcommittees.
  - The structure and function of the PTCC subcommittees.
  - The procedures to be used in designating members to serve on such subcommittees.
  - The responsibilities of the subcommittee members.

## BACKGROUND

- PTCC subcommittees have been established to develop guidance for sponsors and applicants and to address emerging technical problems and management issues (see Attachment A). These subcommittees perform most effectively when each subcommittee's objectives and the responsibilities of its members are clearly defined. The work of each subcommittee also should be effectively communicated both within and outside the Center for Drug Evaluation and Research (CDER). The establishment and function of PTCC subcommittees must be clear to ensure effective

use of staff resources and consistency between CDER management views and Food and Drug Administration (FDA) regulations and policies. To achieve these objectives, CDER has established a coordinating committee, the PTCC.

## ORGANIZATION

The following descriptions and explanations should be applied on a general basis.

- **PTCC**

  - **Chair —** The PTCC Chair is the Office of New Drugs (OND) Associate Director for Pharmacology and Toxicology or a designated representative.

  - **Executive Secretary —** The Chair may act as Executive Secretary, or appoint either a full-time or part-time Executive Secretary to the PTCC.

  - **Members —** Voting members of the PTCC include the Chair, Office of Drug Evaluation (ODE) associate directors for pharmacology and toxicology, supervisory pharmacologists and toxicologists, team leaders, or designees.

  - **Other participants —** With concurrence of the PTCC Chair, nonvoting observers and consultants from other divisions, centers, or Federal government organizations may be included in the activities of the PTCC to facilitate cross-center and/or FDA interactions.

- **Subcommittees and working groups**

  - **Chair and co-chair —** The PTCC will select a chair and co-chair for each subcommittee, taking into account expertise and interest in the subject matter of the subcommittee workload, and organizational and management skills. Chairs and co-chairs should be distributed with the goal of achieving broad representation across the ODEs and other interested offices.

    Each chair should serve for a 3-year term. However, the PTCC will evaluate a chair's position annually and may decide to reduce or extend the term in 1-year increments.

  - **Membership —** Members should be chosen to serve on subcommittees based upon their qualifications, expertise and interest in the subject matter of the subcommittee, their workload, and the demands on their time caused by membership on other subcommittees.

    Invitations for representation should be offered to the ODEs, the Office of Pharmaceutical Science, and other interested CDER offices or FDA centers as is appropriate to the subcommittee goals and expertise desired. Membership should be distributed with the goal of achieving broad representation across the ODEs and other interested offices.

Membership should be kept small (10 or fewer members on core subcommittees) to facilitate efficient operation of each subcommittee.

Generally, membership on subcommittees should be rotated periodically. When desirable, based on expertise or experience, a member's term may be extended. Defined term limits are restricted by the expertise of the current pharmacology/toxicology staff available within the Center. Subcommittee membership should be reviewed annually by the PTCC.

– **Working groups —** Smaller ad hoc working groups (five to seven members) may be established to facilitate productivity of a subcommittee or to work on a short-term project not being addressed by a subcommittee.

## RESPONSIBILITIES

**The PTCC is responsible for:**

- Developing policy on pharmacology/toxicology issues in CDER and making policy recommendations to FDA management
- Serving as a forum for scientific evaluations and decisions involving pharmacology/toxicology issues that cross divisions, offices, and centers
- Providing advice on a consultative basis on pharmacology/toxicology issues in CDER and issues outside of the Center that may involve CDER
- Documenting pharmacology/toxicology practices and policies through prescribed means
- Coordinating, facilitating, and monitoring the efforts of the PTCC subcommittees including: establishing subcommittee structure, function, and membership; assigning topics; approving subcommittee charters; and reviewing final subcommittee documents before transmission to CDER management for clearance
- Establishing good review practices standards for the pharmacology/toxicology reviewers
- Serving as repository for committee and subcommittee recommendations, decisions, and actions
- Promoting and coordinating training, professional development, workshops, and other intramural and extramural activities related to pharmacology/toxicology issues

**The Executive Secretary is responsible for:**

- Organizing and scheduling meetings of the PTCC
- Distributing documents

- Maintaining files of committee activities

- Preparing minutes (meeting minutes will be made available to every committee member) and filing the minutes on a shared drive or internal Web page

**Subcommittees are responsible for:**

- Serving as a source of advice and assistance to the PTCC in responding to CDER staff on matters pertaining to pharmacology/toxicology reviews that are within their areas of expertise

- Participating, as requested by the PTCC or the OND Associate Director for Pharmacology and Toxicology, in the development of policies and procedures related to matters within their areas of expertise

**Chairs of subcommittees are responsible for:**

- Reporting to the PTCC on important issues of general interest as they arise.

- Reporting to the PTCC twice a year to describe the status of any tasks in which they are engaged and to obtain PTCC input and direction. In preparation for each meeting, the chair should provide to the PTCC, at least a week in advance of the meeting, an updated Task List, a summary of achievements since the last report to the PTCC, a projection of activities for the next 6 months, and a list of issues for which PTCC input is needed.

- Developing proposed time frames for completion of projects and forwarding the time frames to the PTCC for concurrence. The PTCC may amend the priorities of the projects assigned, as necessary.

- Scheduling and conducting meetings of the subcommittee as required to fulfill the subcommittee's objectives. The co-chair shall call and run meetings in the absence of the chair.

- Preparing an agenda and distributing it to the subcommittee members in advance of each subcommittee meeting.

- Preparing brief minutes of each meeting and distributing them to the members of the PTCC. Minutes also should be filed electronically on the designated shared drive or Web page under the subdirectory established for each subcommittee.

- With the assistance of the subcommittee members, creating and maintaining a Task List for the subcommittee describing major tasks the subcommittee is undertaking, projected milestones and completion dates, and the current status of each project.

- Maintaining a list of consults, with copies of the consults filed.

**Members of subcommittees are responsible for:**

- Actively participating in subcommittee activities.

- Regularly attending the meetings of the subcommittees for which they are the designated representatives. If a member cannot attend a meeting, an alternate may be designated to attend, with the concurrence of the chair.

## PROCEDURES

- **Meetings** — PTCC meetings should be held monthly, with additional meetings scheduled as needed.

- **Voting** — At least 75 percent of the PTCC voting members must be present for voting on issues to occur. If unanimous agreement is not reached on an issue brought to the PTCC for a vote, areas of disagreement should be documented in the PTCC minutes.

- **Minutes** — All PTCC meetings will result in minutes documenting issues presented to the PTCC membership, and announcing committee decisions and rationales. Copies of the minutes will be distributed to PTCC members. Recommendations made by the PTCC will be delivered to the person or organization which sponsored the discussion for their disposition and action.

- **Establishment of subcommittees**

  – Suggestions for the creation of new subcommittees, including ad hoc working groups that may report to the PTCC or a subcommittee directly, should be made in writing to the PTCC (see Attachment B) by a reviewer or first-line or higher level supervisor in CDER.

    Each suggestion should be accompanied by a brief statement of the proposed objectives of the subcommittee, and may include the names of persons who might serve on the subcommittee as members and as chair and co-chair, the expected frequency of meetings, and the subcommittee's expected life (e.g., 3 months, on-going).

  – The PTCC will determine whether the subcommittee should be established and will notify pharmacology/toxicology reviewers and other affected CDER staff of the creation of a new pharmacology- and toxicology-related subcommittee. A list of current subcommittee members will be maintained by the PTCC.

  – Changes in the membership or objectives of a subcommittee should be submitted to the PTCC for concurrence.

- **Disbandment of subcommittees or working groups**

  – A subcommittee shall be disbanded when:

    - It reaches the end of its scheduled lifetime
    - It has fulfilled its objectives
    - The PTCC determines the subcommittee is not fulfilling a necessary function in the Center

  – Every year, the PTCC shall review the list of subcommittees to determine whether any of the subcommittees on the list should be disbanded or the membership or chair changed. If, after discussions with the chair of the subcommittee, it appears that a subcommittee no longer performs a useful function, the PTCC shall issue a notice that the subcommittee will be disbanded.

- **Communications between CDER pharmacologists/toxicologists and management**

  – The activities of the PTCC will be communicated to the pharmacology/toxicology reviewers through distribution and electronic filing of the minutes of the PTCC meetings.

  – CDER pharmacologists/toxicologists may raise issues to the PTCC by bringing them to the attention of:

    - Their supervisor or team leader
    - A subcommittee chair
    - An ODE associate director
    - The Associate Director for Pharmacology and Toxicology
    - Any PTCC member
    - The PTCC Executive Secretary

## EFFECTIVE DATE

- This MAPP is effective upon date of publication.

## Attachment A

## PTCC Subcommittees and Working Groups[1]

- Arteritis
- Biologics
- Botanicals
- Carcinogenicity Assessment
- Clinical Pathology
- Combinations/Reformulations
- Education
- Genetic Toxicology
- Immunotoxicity
- Inactive Ingredients
- Information Technology
- Neurotoxicity Assessment
- Nonclinical Pediatric Cardiotoxicity
- Nonclinical Pharmacogenomics
- Nonclinical Safety Testing for Pediatric Drugs
- Phospholipidosis
- Photocarcinogenicity Policy
- Reproductive Integration
- Reproductive Toxicity
- Research
- Retreat Planning
- Safety Pharmacology
- Starting Dose
- Statistical

[1] The activity status of the subcommittees varies.

**Attachment B**

**Recommendation for the Creation of a**
**CDER PTCC Subcommittee or Working Group**

**1. Name of Subcommittee:**

**2. Objectives:**

**3. Composition:**

Chair:

Co-Chair:

Membership:

**4. Meeting Frequency:**

**5. Completion Date:**

Concur:_____ Nonconcur:

_____
Chair, PTCC Date