

PROJECT MANAGEMENT

**OFFICE OF NEW DRUGS REGULATORY PROJECT MANAGEMENT
COORDINATING COMMITTEE**

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PURPOSE

This MAPP describes:

- The roles and responsibilities of the Regulatory Project Management Coordinating Committee (RPMCC);
 - The procedures for establishing RPMCC subcommittees;
 - The structure and function of the RPMCC and its committees;
 - The procedures for designating members to serve on the subcommittees; and
 - The responsibilities of those designated to serve on the subcommittees.
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BACKGROUND

The Office of New Drugs (OND) has formed many committees and working groups to address various project management issues. Coordination of these committees ensures effective use of staff resources and establishes and promotes consistent project management policy throughout OND. To achieve these objectives, OND has established a coordinating committee, the RPMCC.

ORGANIZATION

The following descriptions and explanations apply on a general basis. There may be some fluctuation in implementation due to workload demands:

- **RPMCC** – The RPMCC has two major components:
 1. **RPMCC** – The RPMCC consists of the OND Associate Directors for Regulatory Affairs (ADRAs) and all of the OND Chiefs, Project Management Staffs (CPMS)

and the Special Assistant to the Director, OND. The monthly CPMS meeting will be used to present issues to the full RPMCC.

2. **Executive RPMCC (ERPMCC)** – The ERPMCC consists of the OND ADRA's. The ERPMCC will manage routine matters that come before the RPMCC. At the discretion of the ERPMCC, matters that merit broader input will be brought before the full RPMCC for discussion.
 - **Chair** – The position of Chair of the RPMCC/ERPMCC will rotate among members of the ERPMCC, with each term lasting 6 months.
 - **Executive Secretary** – The position of Executive Secretary will rotate among the members of the ERPMCC, with each term lasting 6 months.

- **Subcommittees**

1. **Subcommittee Chairs and Vice-Chairs (or Co-Chairs)** ~~X~~ For each subcommittee, the ERPMCC will select a Chairperson and a Vice- or Co-Chair, taking into account expertise and interest in the subject matter of the subcommittee, workload, and organizational and management skills. Alternatively, the ERPMCC may delegate selection of the Chairperson and Vice- or Co-Chair to the subcommittee membership.
2. **Membership** ~~X~~ Subcommittee membership is not restricted to OND. Members should be chosen by the subcommittee Chair and subcommittee Co-Chair with input from the RPMCC, taking into account their qualifications, expertise, workload, interest in the subject matter of the subcommittee, and the demands on their time caused by membership on other committees. In general, no person should serve on more than two subcommittees at one time. Membership should be distributed with the goal of achieving broad representation within OND, provided that the individuals selected possess adequate experience and skills to address the work of the subcommittee. Members who do not contribute to the work of the subcommittee (i.e., do not attend meetings) will be removed from the member roster.

To facilitate productivity of the subcommittees, use of smaller, short-term ad hoc working groups to address specific issues is encouraged. Subcommittees may create working groups on specific issues bringing in additional expertise as necessary.

RESPONSIBILITIES AND PROCEDURES

- **RPMCC will:**
 1. Provide advice to the Center, Agency, Department, and regulated industry on project management as well as other review management issues that involve OND
 2. Develop strategies for accomplishing long- and short-term project management goals in OND

3. Develop, recommend, and document policies and procedures (MAPPs) relating to project management
 4. Coordinate, facilitate, and monitor the efforts of the RPMCC subcommittees. This will include helping resolve jurisdictional issues that might affect other technical committees (e.g., CMC CC), divisions, offices, or centers
 5. Promote and support professional development workshops and other intramural and extramural activities related to project management
 6. Promote and support the Office of Training and Communications (OTCOM) training in project management, team-building and related management approaches, and in providing regulatory expertise for CDER staff
- **The ERPCC will:**
 1. Meet monthly to address issues that come before the RPMCC
 2. Establish new subcommittees as needed, generally in consultation with the full RPMCC
 3. Modify or disband subcommittees when they are no longer needed
 4. Make decisions on routine matters, including budget and requests for speakers
 5. Determine which issues should be brought before the full RPMCC. Such issues would normally include large budget expenditures, controversial issues, or any issue that would have a significant impact on the project managers.
 - **The Chair of the RPMCC will:**
 1. Provide overall direction to the proceedings of the RPMCC
 2. Coordinate with the ERPCC requests for speakers on project management issues
 3. Arrange and organize monthly meetings of the RPMCC. When appropriate, issues will be brought to the full RPMCC in a monthly CPMS meeting
 4. Communicate RPMCC activities to Center management when appropriate or when requested
 - **The Executive Secretary of the RPMCC will:**
 1. Document decisions made by ERPCC and file on the PMCC shared drive ([\\cds013\pmcc](#)) using the following format: pmcc\erpmcc\minutes\year-month-day
 2. Maintain on the common shared drive a current list of project management-related subcommittees, a brief description of the issues the subcommittees are addressing, and subcommittee members

- **Subcommittees will:**

1. Complete projects assigned by RPMCC within agreed-upon time frames
2. Ensure that proposals for programs, policies, and procedures developed by the subcommittees are submitted to ERPMCC for review and approval prior to broader circulation for comment
3. Establish working groups, as necessary, to bring in additional expertise on specific issues

- **Chairs/Co-Chairs of Subcommittees will:**

1. Report to the RPMCC at least annually to describe the status of all projects in which they are engaged, and obtain RPMCC input and direction
2. Schedule and conduct meetings to fulfill the subcommittee's objectives. The Vice-Chair assumes the responsibilities of Chair in his/her absence.
3. Ensure preparation of brief minutes of each subcommittee meeting, distribute them to subcommittee members, and post on the PMCC shared drive using the following format: pmcc\subcommittee name\minutes\year-month-day
4. Maintain appropriate files on committee work
5. With assistance of the subcommittee members, create and maintain 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
6. Obtain input from ERPMCC on documents proposing programs, policies, or procedures prior to distribution to individuals or groups outside the Center or to CDER staff other than the RPMCC or its subcommittees

- **Members of Subcommittees will:**

1. Represent the views of their discipline, division, or office on issues considered by the subcommittee
2. Obtain concurrence from management for their participation on the subcommittee and communicate with their discipline, division, or office management (whichever is appropriate) regarding the deliberations of the subcommittee
3. Regularly attend the meetings of the subcommittees for which they are designated members, and contribute to the work of the committee

EFFECTIVE DATE

This MAPP is effective upon date of publication.