DISCIPLINE SPECIFIC

ADMINISTRATIVE MANAGEMENT COORDINATING COMMITTEE

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PURPOSE This MAPP describes:

- The role and responsibilities of the Administrative Management Coordinating Committee (AMCC);
- The procedures to be used for establishing administrative committees in the Center for Drug Evaluation and Research (CDER);
- The structure and function of the various committees;
- The procedures to be used in designating members to serve on such committees; and the responsibilities of those designated to serve on such committees.

BACKGROUND

CDER administrative committees have been established to develop guidelines for use by the various programs and to address administrative streamlining initiatives, i.e., non-clerical program support activities such as travel, facilities, payroll, budget/procurement, etc. These committees perform most effectively if the objectives

of the committee and the responsibilities of its members are clearly defined. The work of each committee should be effectively communicated to all CDER program areas. The establishment and function of administrative committees must be done to ensure effective use of staff resources. To achieve these various objectives, CDER has established a coordinating committee, the AMCC.

ORGANIZATION

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

- **AMCC**

  1. **Chair -** The AMCC Chair is the Deputy Director, OM or a designated representative.

  2. **Executive Secretary -** The Chair may appoint an Executive Secretary/Project Manager to the AMCC.

  3. **Members -** Voting members of the AMCC core committee include one representative each from the Offices of the Center Director, Compliance, and Training and Communication, and two representatives from the Offices of Review Management, Pharmaceutical Science and Management. The Chair of the committee counts as one of the voting members for OM.

  4. **Other Participants -** With concurrence of the AMCC Chairperson, non-voting observers and consultants from other Division/Centers or Federal government organizations may be included in the activities of the AMCC to facilitate cross Center and/or agency interactions.

- **Subcommittee and Working Groups**

  Suggestions for the creation of new committees, including ad hoc working groups that may report to the AMCC directly or to a Subcommittee, should be made in writing (see Attachment B) by a first-line or higher level supervisor in CDER to the AMCC or by a member of the AMCC. A member of the core committee will either chair or facilitate a subcommittee.

  The AMCC will determine whether the committee should be established and will notify the CDER Senior Management Team of the creation of a new

administrative related committee. A list of current committee members will be maintained by the AMCC.

Changes in the membership or objectives of a committee should be submitted to the AMCC for concurrence.

1. **Chair and Co-Chair -** The AMCC will select a Chairperson and a 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 between the Offices in the Center.

   Each Chairperson should serve for a two-year term. The AMCC may, however, evaluate a Chair's position annually and may, in unusual circumstances, decide to reduce or extend the term in one-year increments.

2. **Membership -** Members should be nominated to serve on subcommittees/working groups 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 committees.

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

   Membership on subcommittees should normally be rotated periodically, e.g., every two years. However, during the original establishment of a subcommittee, half of the subcommittee should serve for one year rather than two to ensure that not all members are rotating at the same time. When desirable, based on expertise or experience, a member's term may be extended. Committee membership should be reviewed annually by the AMCC.

   To facilitate productivity of the subcommittees, the use of smaller ad hoc working groups (5 to 7 members) to address specific issues may be used.

RESPONSIBILITIES

- **The AMCC is responsible for:**

  1. Providing advice on a consultative basis on administrative issues in CDER and administrative issues outside of the Center/Agency/Department that may involve CDER;

  2. Developing/recommending policy on administrative issues in CDER;

  3. Documenting administrative policies through prescribed means;

  4. Serving as liaison between administrative working-level groups and management in the Center;

  5. Coordinating, facilitating, and monitoring the efforts of the administrative subcommittees including: establishing committee structure, function, and membership; assigning topics; reviewing and approving final committee products before transmission to CDER management for clearance;

  6. Establishing and implementing standard operating procedures (SOP) for administrative practices;

  7. Serving as repository for committee recommendations, decisions, and actions; and

  8. In conjunction with OTCOM, promoting and coordinating training, research, professional development, workshops, and other intramural and extramural activities related to administrative issues.

- **The Executive Secretary is responsible for:**

  1. Arranging and organizing meetings. Issues to be brought before the AMCC should be directed to the attention of the Executive Secretary who will attempt to schedule them in consultation with the Chair of the AMCC;

  2. Distributing documents;

  3. Maintaining files of committee activities;

  4. Preparing minutes to be made available to every committee member;

5. Ensuring the accuracy of AMCC documents;

6. Establishing a CDER shared drive (x: drive) directory for the AMCC. File all documents to appropriate AMCC shared drive directory or subdirectory;

7. Budget for committee; and

8. Approving funds for travel for members, administrative retreats, and any other expenditures financially supported by the AMCC.

- **Subcommittees are responsible for:**

1. Serving as a source of advice and assistance to AMCC in responding to CDER staff on administrative matters that are within their areas of expertise;

2. Developing, as needed, policies and procedures related to matters within their areas of expertise; and

3. With approval from AMCC, establishing working groups on specific issues, bringing in additional expertise as necessary.

- **Chairs of Subcommittees are responsible for:**

1. Reporting to the AMCC twice a year to describe the status of any tasks in which they are engaged and to obtain AMCC input and direction;

2. Developing proposed time frames for completion of projects and forwarding them to AMCC for concurrence. The AMCC may amend the priorities of the projects assigned, if necessary;

3. 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 Chairperson;

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

5. Preparing brief minutes of each meeting and distributing them or notifying the members of the AMCC;

6. Ensuring that copies of all records of subcommittee meetings and other deliberations of the committee are placed in a file maintained by the Executive Secretary for AMCC and filed on the x drive;

7. 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; and

8. Reporting semi-annually to the AMCC on the activities of the subcommittee. In preparation for each meeting, the Chairperson should provide to the AMCC at least a week in advance of the meeting, an updated Task List, a summary of achievements since the last report to the AMCC, a projection of activities for the next six months, and a list of issues for which AMCC input is needed.

- **Members of Subcommittees are responsible for:**

1. Representing their Division's/Office's views on issues considered by the subcommittees that pertain to their areas of responsibility;

2. Communicating with their Division/Office management about the deliberations of the subcommittees; and

3. 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 Chairperson.

PROCEDURES

- **Meetings** of the AMCC should be held <u>at least</u> monthly or as needed.

- **Voting** - At least 51% of the voting members of the AMCC must be present for voting on issues to occur. If unanimous agreement is not reached on an issue brought to the Committee for a vote, areas of disagreement should be documented in the AMCC minutes.

- **Reports** - All AMCC meetings will result in reports documenting issues presented to the AMCC membership, and announcing committee decisions and their rationale. Copies of the reports will be distributed to AMCC members and

the original reports will remain with the Committee Chairperson and/or the Executive Secretary. Recommendations made by the AMCC will be delivered to the person or organization which sponsored the discussion for their disposition and action.

- **Disbandment of Subcommittees or Working Groups** - A subcommittee shall be disbanded when:

  1. It reaches the end of its scheduled lifetime;

  2. It has fulfilled its objectives; or

  3. The AMCC determines the committee is not fulfilling a necessary function in the Center.

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

- **Communications Between CDER AMCC and Management**

  1. The activities of the AMCC will be communicated to the Office Directors, Division Directors, and Management Officers through distribution and electronic filing of the minutes of the AMCC and subcommittee meetings.

  2. CDER employees may raise issues to the AMCC by bringing them to the attention of:

     a. Their AMCC representative;

     b. A subcommittee Chairperson; or

     c. Any AMCC member.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment A

ADMINISTRATIVE SUBCOMMITTEES

Committee

Human Resources

Facilities

User Group (Senior Management Officers)

Budget/Procurement

Travel

Training

Payroll

IT for Administrative Issues

Attachment B

RECOMMENDATION FOR THE CREATION OF A CDER AMCC SUBCOMMITTEE OR WORKING GROUP

1. **Name of Committee:**

2. **Objectives:**

3. **Composition:**

   Chairperson:

   Co-Chair:

   Membership:

4. **Meeting Frequency:**

5. **Completion Date:**

   Concur:_____ Non-Concur:_____

   _____ _____
   Chairperson, AMCC Date