OFFICE OF THE CENTER DIRECTOR

Research Coordinating Committee (RCC)

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PURPOSE

- This MAPP describes the organizational structure, roles, and responsibilities of the Research Coordinating Committee in the Center for Drug Evaluation and Research (CDER).

BACKGROUND

- A Research Coordinating Committee (RCC) has been established to ensure that CDER's regulatory research efforts are focused on those areas that will provide the greatest benefit to the Agency and the public, and to ensure coordination of activities within CDER and, when necessary, between CDER and other Centers. The responsibilities of the RCC are (1) to enhance and strengthen coordination and communication of research activities within CDER and between CDER and other FDA and DHHS organizations, (2) to provide guidance on priority areas for CDER research activities, (3) to recommend priorities for research activities to Center management, and (4) to facilitate the identification, recognition, and visibility of CDER's science and research staff.

DEFINITION

- **Research:** "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102(d)). Some examples of research activities include, but are not limited to, clinical investigations involving human subjects, animal research, conducting surveys, quality standards development, bioavailability/bioequivalence (BA/BE) methods for complex drug substances and drug products, epidemiological research studies, methodological and regulatory research in support of critical path initiatives, new clinical trial designs, scientific computational strategies for combinatorial toxicology, disease modeling and clinical trial simulation, and other related areas.

ORGANIZATION

- **Chair** — The RCC Chair is the Deputy Center Director.

- **Project Manager** — The Executive Operations Staff (EOS) in the Office of Executive Programs will appoint a project manager to coordinate activities of the committee.

- **Members** — In addition to the Chair and Project Manager, the RCC will include the following members:

    1. An individual or designee from each of the following Center organizations and committees:

        - CDER Cooperative Research and Development Agreement (CRADA) Contact
        - CDER liaison to the DHHS Research Coordination Council (RCC)
        - CDER liaison to the FDA Research Involving Human Subjects Committee (RIHSC)
        - CDER representatives to FDA's Senior Science Council (SSC)
        - Chair of the CDER Regulatory Science and Review (RSR) Committee
        - Office of Clinical Pharmacology and Biopharmaceutics (OCPB)
        - Office of Counterterrorism and Pediatric Drug Development (OCTAP)
        - Office of Medical Policy (OMP)
        - Office of New Drugs (OND)
        - Office of Pharmaceutical Science (OPS)
        - Office of Pharmacoepidemiology and Statistical Science (OPASS)
        - Office of Training and Communication (OTCOM)
        - Committee on Scientific Computing

    2. Individuals from other FDA Centers, the Agency, or other Federal Government agencies as needed to facilitate cross-Center and/or Agency interactions on an ad hoc basis.

- **Subcommittees and Working Groups**

    1. The RCC may form subcommittees or working groups to review scientific issues, make recommendations, or implement activities related to the function of the RCC. Chairs, co-chairs, and members of subcommittees will be selected by the RCC. Working groups may be formed by either the RCC or by RCC subcommittee, subject to approval by the RCC.

    2. When possible, the RCC will draw upon existing CDER working groups and committees.

RESPONSIBILITIES

- **The RCC will:**

    1. Establish policies and procedures related to the conduct of CDER research to ensure that CDER scientific research is

a. Conducted in a manner consistent with CDER's mission, vision, and values; and,

b. Conducted in a manner consistent with FDA and DHHS policies and requirements.

2. Establish a mechanism for tracking and reporting CDER research projects and activities.

3. Educate and communicate with CDER staff on research policies, priorities, and sources of information.

4. Develop a strategic plan for CDER research activities in collaboration with the senior management team of the Center.

5. Provide advice and assistance to CDER scientific research programs (including RIHSC, DHHS RCC, RSR, and SSC) and program managers on all research priorities and policies.

6. Coordinate CDER participation on the FDA Science Board and in Science Forum meetings and workshops.

7. Coordinate responses to questions on research activities in the Center.

8. Facilitate the identification and recognition of outstanding CDER staff for science and research achievement awards.

- **The RCC Chair will:**

1. Ensure that recommendations developed by the Committee are communicated to the Center Director and to Center management.

2. Ensure that RCC meetings are held as needed.

3. Ensure that all CDER constituencies have input into the RCC.

4. Chair meetings of the RCC.

- **The Project Manager will**:

1. Arrange and organize meetings. Issues to be brought before the RCC should be directed to the attention of the Project Manager, who will schedule them in consultation with the Chair of the RCC.

2. Serve as the primary point of contact for coordinating and responding to information requests on research activities from the Office of the Commissioner and DHHS.

3. Maintain a repository of information on all research activities in the Center and the costs related to those activities. This responsibility may include training other individuals to enter data into a centralized database.

4. Maintain files of Committee activities.

5. Ensure the accuracy of RCC documents.

- **The Subcommittees will:**

1. Serve as a source of advice and assistance to the RCC.

2. Undertake specific tasks designated by the RCC.

3. With approval from the RCC, establish working groups and/or solicit input from existing working groups on issues related to scientific support and scientific research activities.

4. Report subcommittee activities to the RCC on a regular basis.

5. Develop proposed time frames for completion of projects and forward them to RCC for concurrence.

6. Ensure that copies of all records of subcommittee meetings and other deliberations are provided to the Project Manager of the RCC.

- **CDER Staff will:**

Become familiar with and responsive to Center policies and procedures related to the conduct of research.

EFFECTIVE DATE

This MAPP is effective upon date of publication.