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**Office of Review Management**

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**Information Technology Committee (ITC)**

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**PURPOSE**

This MAPP describes the role and responsibilities of the Center for Drug Evaluation and Research's (CDER) Office of Review Management Information Technology Committee (ORM ITC) in facilitating transition to an Electronic Regulatory Submission and Review (ERSR) process and addressing specific information technology issues affecting all ORM staff.

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**BACKGROUND**

CDER oversight of information technology is the responsibility of the Information Technology Committee (ITC). ORM has representation on the ITC through the Associate Director for Electronic Review, ORM.

The ORM ITC is established to provide a systematic mechanism for:

- Obtaining input from key ORM staff on issues being considered by the ITC;
- Raising issues of concern to ORM staff to the ITC;
- Monitoring, defining, implementing and refining the ERSR strategy, including the needs of ORM review disciplines; and
- Addressing information technology problems facing ORM staff related to the use of its

current and proposed information technology systems.

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## REFERENCES

CDER MAPP 7600.1, *Management of CDER Information Technology Coordinating Committee*, February 24, 1997.

CDER MAPP 4510.2 *Clearance of Speeches, Articles and Other Communication Material*, November 7, 1995

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## ORGANIZATION

The ORM ITC consists of representatives from each of the divisions and staffs of ORM. Membership in the ORM ITC will be determined as follows:

- **Chair:** The Associate Director for Electronic Review, ORM, will serve as the Chair of the ORM ITC and will nominate a technical specialist to serve as Vice-Chair with the concurrence of the Deputy Center Director (Review Management).
- **Members:** Each division within ORM will be represented by one reviewer or project manager nominated by the division director. In addition, each office will be represented by one technical specialist or other representative nominated by each office director. There will also be two representatives from the immediate office of ORM nominated by the Deputy Center Director (Review Management). The Chair may select other individuals as needed to achieve the goals of the ORM ITC.
- **Executive Secretary:** The Chair will select an individual to serve as Executive Secretary of the ORM ITC.
- **Working groups:** Working groups will be formed by the ORM ITC Chair as necessary to address specific issues.

## RESPONSIBILITIES

### **ORM ITC is responsible for:**

- Serving as the primary ORM focus for all activities including policy development and prioritization regarding information technology, including all issues related to ERSR;
- Serving as liaison between ORM staff and ORM senior management regarding information technology issues;
- Providing advice to ORM senior management on information technology issues involving ORM, including proposed information technology initiatives, software/hardware upgrades, and major technology decisions;
- Ensuring communication and standardization among ORM staff with regard to information technology systems and products; and
- Producing an annual information technology plan defining long-term and short-term goals in concurrence with CDER's Information Technology Coordinating Committee (ITCC) objectives and anticipated resources.

### **The ORM ITCC Chair is responsible for:**

- Developing agendas for, and leading meetings of the ORM ITC;
- Providing information technology issue updates to ORM ITC members between meetings;
- Presenting information from CDER's ITCC meetings to ORM ITC members and ORM senior management;
- Gathering comments and related information on issues pending consideration before the ITC;
- Setting up working groups to address specific information technology issues;
- Reviewing and approving all speaker requests and meeting requests regarding

information technology and ORM;

- Reviewing and approving the contents of speeches, articles, and other communication material regarding information technology and ORM, and
- Developing, monitoring, and refining ORM information technology policies and strategies for presentation to the ORM ITC, CDER's ITCC, and the Deputy Center Director (Review Management), as appropriate.

**The Executive Secretary is responsible for:**

- Scheduling regular meetings of the ORM ITC;
- Preparing and distributing agendas for meetings to Committee members;
- Preparing minutes of meetings;
- Tracking and coordinating the approval of speaker requests involving information technology and ORM; and
- Making related materials available to Committee members and ORM staff, as appropriate, through the CDER network and other means as appropriate.

**Working Groups are responsible for:**

- Addressing the issues put forth by the Committee Chair;
- Reporting their findings to ORM ITC.

**Committee members are responsible for:**

- Providing feedback from ORM ITC meetings and communicating with their individual divisions and offices, as appropriate;
- Raising issues to the ORM ITC Chair that are of concern to their divisions and offices;
- Sharing information on information technology projects within their divisions, including current status and techniques employed with the Committee; and

- Monitoring the progress of information technology strategies as implemented in their individual divisions.

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## **PROCEDURES**

All ORM information technology issues should be brought to the attention of the ORM ITC Chair.

The ORM ITC will meet quarterly with additional meetings arranged on an as-needed basis to address specific issues. Between meetings, the ORM ITC members will communicate with the ORM ITC Chair to raise specific issues.

The ORM ITC Chair will communicate with the ORM ITC to raise specific issues, gain feedback and provide information;

Working groups will meet as required by the issues they are addressing and provide an update of their progress to the ORM ITC Chair.

ORM ITC meetings will be open to ORM staff, particularly those with an involvement in the items identified in the meeting's agenda.

Periodically, others will be invited to attend meetings in an attempt to discuss information of interest to the ORM ITC. These may include others within the agency (e.g., Office of Pharmaceutical Science, Office of Information Technology, other governmental agencies, hardware and software vendors).

The ORM ITC members will serve for a period of one year. At the end of the term, division or office directors, as appropriate, may designate new individuals to represent them. In the absence of such designations, current members will continue to serve.

In case of departure of a member, the corresponding ORM division, or office director, as appropriate, will designate a replacement.

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## **EFFECTIVE DATE**

This MAPP is effective upon date of publication.