

OFFICE OF TRANSLATIONAL SCIENCES

Management of the Regulatory Science and Review Enhancement (RSR) Committee¹

CONTENTS

PURPOSE
BACKGROUND
ORGANIZATION
RESPONSIBILITIES
PROCEDURES
EFFECTIVE DATE

PURPOSE

This MAPP describes:

- The role and responsibilities of the Center for Drug Evaluation and Research (CDER) Regulatory Science and Review Enhancement (RSR) Committee
 - The structure and function of the RSR Committee
 - The responsibilities of those designated to serve on the RSR Committee, the Co-Chairs of the Committee, RSR project manager, RSR applicants, and RSR awardees
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BACKGROUND

- As part of the Agency's mission to ensure that safe and effective drugs are available to the American people, CDER seeks to enable, support, and effectively use regulatory science and review enhancement projects initiated by Center scientists.

The primary purpose of such projects is to assist Agency management and staff in the following areas:

1. Making better use of the information available to the Agency
2. Meeting the regulatory objectives of CDER
3. Disseminating to regulated industry relevant scientific information on planning and designing drug trials and analyzing data from these studies

The secondary purpose of these projects is to support CDER staff through professional development activities.

¹ MAPP 7700.1 is a revision and renumbering of previous MAPP 4112.5.

ORGANIZATION

1. **Oversight** – The Director of the Office of Translational Sciences (OTS) will provide oversight for the RSR activities.
 2. **Co-Chairs** – The Co-Chairs of the RSR Committee are designated by the Deputy Center Director. At least one Co-Chair of the RSR Committee will be appointed to the Research Coordinating Council (RCC) to provide updates on RSR activities and bring any issues and/or concerns to the RCC.
 3. **Project Manager** – The Project Manager is designated by the Director of OTS.
 4. **Voting Members** – In addition to the Co-Chairs, members of the RSR Committee include representatives from various scientific disciplines in CDER. Members are designated by the RSR Co-Chairs and approved by the Director of OTS.
 5. **Non-Voting Members** – Non-voting members may be appointed to the RSR Committee to provide expertise in policy areas that may affect the evaluation of proposals. For example, a non-voting member representing CDER's Office of Information Technology is designated by the Director of OIT and approved by the RSR Chair and the Director of OTS to ensure that proposals are in conformance with CDER guidelines governing the use of non-standard software.
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RESPONSIBILITIES

- **The RSR Committee will:**
 1. Evaluate research proposals based on CDER priorities, impact, scientific merit, feasibility, and budget.
 2. Assist in the identification of CDER regulatory science research needs and priorities to facilitate the solicitation of proposals.
 3. Ensure that the RSR Committee efforts are focused on the scientific areas that will provide the greatest benefit to the Agency's mission and the public health.
 4. Provide advice to the Director of OTS on RSR projects to be funded.
- **The Co-Chairs of the RSR will:**
 1. Ensure that the responsibilities of the RSR Committee are implemented in accordance with this MAPP and other Agency and Center policies and procedures.
 2. Ensure that recommendations developed by the RSR Committee are communicated to the Director of OTS.
 3. Set the agenda and facilitate all meetings.
 4. Ensure that all CDER constituencies have input into the RSR process and that all CDER RSR projects are reviewed by the RSR Committee.

• **The Project Manager will:**

1. Schedule and coordinate meetings. Issues to be brought before the RSR Committee should be directed to the attention of the Project Manager, who will notify the Co-Chairs.
2. Draft CDER-wide announcements regarding the RSR program for review by Co-Chairs before distribution.
3. Act as liaison between the award applicants and the RSR Committee throughout the entire funding cycle, keeping them informed on the status of their proposals.
4. Manage all correspondence and documents related to the RSR review process.
5. Maintain electronic and paper files of RSR Committee activities.
6. Prepare minutes of the meetings and distribute to all Committee members within 2 weeks of the meeting.
7. Track status of all RSR projects, including numerical scores, rankings, and funding decisions. Maintain summary tables of these data.
8. Ensure the accuracy and completeness of RSR applications and other RSR documents.
9. Notify awardees of Committee funding decisions, and ensure that awarded funds are routed to the appropriate office.
10. Collect Progress Reports and Final Reports from RSR investigators.
11. Coordinate RSR Presentation Day for RSR investigators to present their findings and/or results.
12. Coordinate review of funded projects involving research in human subjects to determine the need for review by the FDA Research Involving Human Subjects Committee (RIHSC).
13. Ensure that the project principal investigator (PI), title, and PI office information for each funded project is entered into the CDER Research Database.
14. Ensure that information and slide presentations from RSR-funded projects are posted to the appropriate CDERnet Web site in a timely manner.

• **The RSR Applicant will:**

1. Be a CDER reviewer or research scientist who has an appointment of at least 1 year.
2. Address the following areas in the RSR application:
 - Impact on the quality or efficiency of the IND or NDA process
 - Scientific merit
 - Cost
 - Probability of success
 - Knowledge, skills, and experience of the investigator
3. Follow the Office of Management and Budget guidelines regarding the Paperwork Reduction Act of 1995, which mandates that all collections of information from the public are conducted in the least burdensome method possible.

4. Comply with Federal regulations for the protection of human subjects (45 CFR part 46, 21 CFR part 50, 21 CFR part 312).
 5. Follow the process for approval for all information technology (IT) projects through the Information Management Steering Committee.
- **The RSR Awardees will:**
 1. Assume primary responsibility for completing the project and adhering to the allotted budget.
 2. Complete the Progress Report and Final Report for their RSR project as requested by the Project Manager.
 3. Present their findings and/or results at the Center's RSR Presentation Day.
 4. Notify the project manager in a timely manner (within 30 days of deadline) if they cannot complete their project, provide progress reports, or present at the RSR Presentation Day.

RSR Awardees who do not adhere to these rules will not be eligible to receive RSR funding for 2 years after the due date of their project.

PROCEDURES

- **Review cycle process:**
 1. Priorities for funding under the RSR program will be established by CDER management, the RCC, and the RSR Committee.
 2. The Project Manager will issue an announcement of research priorities and available funding, requesting that interested candidates in CDER submit concept papers describing potential projects.
 3. Interested applicants must adhere to all RSR guidelines and requirements distributed in the CDER All Hands announcement. Applications will receive a preliminary review for completeness. If there is sufficient time before the submission deadline, those that do not adhere to the RSR guidelines will be returned for revision. Non-compliant applications received at the deadline will not be evaluated.
 4. At least one RSR Committee member will review each concept paper. The Co-Chairs will assign papers to Committee members based on their scientific expertise on the subject matter in the concept paper.
 5. The RSR Committee will meet to rate and rank the concept papers.
 - (a) The RSR members who review a concept paper will present a summary to the Committee with a recommendation on funding. The recommendation will be provided orally and in writing.
 - (b) Committee members present during presentation and discussion of a given concept paper will give it a numerical score based on the reviewer's recommendations.
 - (c) The RSR Committee will determine the number of full proposals to be invited from the concept papers.

6. Applicants whose concept papers are judged to be meritorious will be invited to submit a full proposal.
 7. Full proposals will be submitted to the RSR Committee, accompanied by a signed letter of intent. The applicant and his or her supervisor, division director, and office director will sign the full proposal and letter of intent.
 8. At least one RSR Committee member and at least one ad hoc reviewer from the appropriate discipline will review each proposal. RSR Committee members will submit names of ad hoc reviewers for consideration. Ad hoc reviewers cannot be the Principal Investigator's or Co-Investigator's direct supervisor or direct subordinate.
 9. The RSR Committee will meet to rate and rank the full proposals.
 - (a) The RSR Committee members who review the proposal will present a summary to the Committee with a recommendation on funding. The recommendation will be provided orally and in writing. The discussion will include the ad hoc reviewer's comments.
 - (b) Each proposal will be rated on a numeric scale by Committee members who are present at the meeting when the concept paper is presented and discussed.
 - (c) The total amount of available funding will determine the number of proposals that will be funded. The proposals with the highest ratings will be selected.
- **Recusal**

Committee members who are direct supervisors of an investigator or collaborator on any proposal must recuse themselves from voting on that individual's concept or full proposal. However, they can stay in the room during discussion of the proposal to answer any specific questions by the Committee members.
 - **Voting**

Projects are ranked based on their average numerical score. Individual votes remain confidential. Only members present during discussion of a particular project may vote.
 - **Quorum**

A simple majority of the members of the RSR Committee must be present to rate projects.
 - **Meetings**

Meetings of the RSR Committee will be scheduled as needed. There will generally be at least three meetings a year, the timing of which will be determined by the funding cycle.

 1. The first meeting is to select priorities for funding based on the Center's research goals and to request concurrence by CDER Senior Management.
 2. The second meeting is to rate and rank concept papers.
 3. The third meeting is to rate and rank the full proposals.
 4. Other meetings may be called as needed by the Co-Chairs of RSR Committee.
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EFFECTIVE DATE

This MAPP is effective upon date of publication.