

PROCEDURES

OFFICE OF TRANSLATIONAL SCIENCES

Management of the Regulatory Science and Review Enhancement Program

Table of Contents

PURPOSE1

BACKGROUND.....1

RESPONSIBILITIES2

PROCEDURES3

REFERENCES4

DEFINITIONS4

EFFECTIVE DATE5

CHANGE CONTROL TABLE5

ATTACHMENT 16

PURPOSE

This MAPP describes

- The roles and responsibilities of the CDER Regulatory Science and Review Enhancement (RSR) Committee
- The structure and function of the RSR Committee
- The responsibilities and expectations of RSR applicants and awardees

BACKGROUND

CDER seeks to employ science and review enhancement projects initiated by Center staff. CDER has an annual call for proposals for RSR funding. Proposals may be submitted by any CDER employee. A CDER-wide notification is sent annually encouraging all disciplines to apply.

The primary purpose of RSR applications is to promote certainty and consistency of regulatory decisions and improve the translation of basic discoveries to viable products. The secondary purpose is to support CDER staff by providing valuable professional development opportunities. RSR projects are funded on a competitive basis. Interested CDER staff must submit a proposal to be considered.

RESPONSIBILITIES

The information below provides the overall responsibilities of the RSR Committee and its members. More details on responsibilities can be found in the RSR Charter.

The Office of Translational Sciences Director:

- Provides oversight for the RSR activities
- Provides funding for RSR activities
- Appoints the RSR Committee Chair
- Appoints Project Manager from OTS Immediate Office
- Issues an annual CDER-wide call for RSR Proposals

CDER Office Directors:

- Nominate staff to serve RSR Committee members for terms of less than 3 years
- Identify individuals to serve on the RSR Committee as voting members

The RSR Committee Chair:

- Includes representatives from various scientific disciplines
- Serves as Chair for a term of 2 years
- Ensures that the responsibilities of the RSR Committee are implemented in accordance with this MAPP, the RSR Charter, and other Agency and Center policies and procedures

The RSR Committee:

- Solicits and reviews proposals
- Oversees the CDER-wide presentation event where findings and results are shared with colleagues
- Ensures efforts are focused on the scientific areas to provide the greatest benefit to the Agency's mission to the public health
- Evaluates research proposals based on CDER priorities, impact, scientific merit, feasibility, and budget
- Ensures applicants are CDER employees
- Discusses proposals during committee voting days
- Provides funding recommendations to the Director of OTS on RSR projects to be funded
- Appoints non-voting members to provide expertise

The Project Manager:

- Coordinates all committee meetings
- Liaises between the RSR applicant and the RSR Committee
- Informs RSR applicants on the status of their proposals
- Coordinates CDER-wide RSR presentation events
- Notifies awardees of RSR opportunities

The RSR Applicant:

- Obtains concurrence from the following elements, prior to submission
 - the Project Lead's first and second line supervisors
 - co-lead(s)
 - all collaborators
- Addresses the following in the RSR proposal
 - impact on the quality or efficiency of the IND or NDA process
 - scientific merit
 - cost (itemized budget)
 - probability of success
 - knowledge, skills, and experience of the investigator
- Follows the HHS guidelines regarding the Paperwork Reduction Act of 1995
 - Comply with all applicable acts, laws and procedures HHS regulations for the protection of human subjects (45 CFR 46, 21 CFR 50, 21 CFR 312)
 - CDER and FDA process for approval for all proposals with information technology components for example; database development, software development/purchase, license issues
 - CDER's requirements for obtaining a research fellow CDER's Oak Ridge Institute for Science and Education (ORISE) Fellowship Program including timelines and administrative fees
 - CDER requirements, procedures, and fiscal timelines for acquiring a contract or grant

The RSR Awardee:

- Serves as project manager for his or her approved project, and ensures that funds are expended within the fiscal year in accordance with the allotted budget
- Utilizes funding only for specifically allocated purposes
- Completes updates as requested by the RSR Project Manager as well as for the CDER Science Projects Database
- Presents findings and results at a CDER-wide RSR presentation event
- Notifies the CDER RSR Program in a timely manner if they cannot complete their project, provide progress reports, or present at a CDER-wide RSR presentation event

Voting Members:

- In addition to the RSR Committee Chair, members of the RSR Committee include representatives from several scientific disciplines in CDER nominated by their respective Office Directors

Non-Voting Members:

- Non-voting members may be appointed to the RSR Committee to provide additional expertise and participate at committee meetings

PROCEDURES

Note: Additional procedures are in the RSR Charter.

Review Cycle Process

The Director of OTS issues an annual CDER-wide call for RSR proposals. This announcement directs potential applicants to information and guidelines for the funding cycle.

1. Interested applicants must adhere to all RSR guidelines and requirements distributed in the CDER-wide announcement. Proposals will receive a preliminary review for completeness. Proposals that do not adhere to the RSR guidelines will be rejected.
2. Submit proposals electronically by the deadline. Late submissions will not be accepted.
3. RSR Committee members are assigned to review proposals. To aid in the evaluation of each proposal,
 - a. Provide expertise in proposal subject matter, and
 - b. Review the proposal for scientific merit, feasibility, and budget considerations.
4. RSR Committee members may identify CDER staff to serve as non-voting reviewers to provide additional expertise during the review cycle. To avoid a conflict of interest, these non-voting members cannot be the Project Leads, Co-Leads, direct supervisor, or direct subordinate.
5. Prior to the Committee meeting, RSR applicants will be given an opportunity to answer questions from RSR Committee members and non-voting members to provide clarification on the proposal, if needed.
6. The RSR Committee will meet to rate and rank the proposals.
7. RSR applicants will be notified via email on the status of awards and availability of funding.
8. Information regarding fiscal year funding will be available on the RSR Web page after funds are awarded.

REFERENCES

1. Paperwork Reduction Act of 1995.
 2. RSR Charter
-

DEFINITIONS

CDER-wide RSR presentation events –Any CDER event where FDA researchers are invited to share the product of their work. (i.e. CDER Innovation Day).

Proposal Collaborators – Any personnel in addition to the Primary Investigator who will be used to collaborate, offer information, or aid in conducting the proposed project.

The RSR Committee – Composed of a Chair, appointed by the Office of Translational Sciences (OTS) Director, and committee members appointed by their respective Office Directors. In addition, there is an OTS project manager assigned to assist the RSR Committee.

EFFECTIVE DATE

This MAPP is effective upon date of publication

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions

ATTACHMENT 1

RSR-Proposal - New Form

Page 1 of 3

http://sharepoint.fda.gov/orgs/CDER-Center-Wide/rsr/ManagerOnly/Forms/AllItems.aspx

RSR Proposal - FY 2015 Cycle

RSR Applications are due by December 8, 2014

Project Lead

Last Name	First Name	Office/Division
<input type="text"/>	<input type="text"/>	<input type="text"/>
Supervisor	Management Officer	<i>if your Office/Division is not listed please type it in</i>
<input type="text"/>	<input type="text"/>	

Project Co-Lead's and Other Study Personnel should be added to the Personnel section

Project Title

Project Topic Area
Select...

Current Project Support

Is this a continuation of an existing RSR Project?	<input type="radio"/> YES <input type="radio"/> NO	IF YES - What is the RSR#?	<input type="text"/>
--	---	----------------------------	----------------------

If proposal builds on results of an ongoing RSR project, please attach most recent progress or final report.

Is your previous RSR Progress/Final Report attached?

Is project receiving other FDA intramural funding? YES NO
If Yes - Please provide the following information - if funding program not on menu, please type in

Funding Program	Project Title	Current Funding Amount
Select...	<input type="text"/>	<input type="text"/>

Project Statement

Public Health or Regulatory Relevance

Please provide a description of the public health or regulatory need for the project.
Limit to 1-2 paragraphs: suggested length no more than 500 words. (note: box will expand to fit text)

http://sharepoint.fda.gov/orgs/CDER-Center-Wide/rsr/_layouts/Print.Form.Server.aspx?XsnLocation=http://shar... 9/22/2014

Projected Outcome and Impact

- Please provide a description of projected outcome(s) and how the completion of the project will contribute to the specified needs and to improving the quality and efficiency of the IND/BLA/NDA review process.

Limit to 1-2 paragraphs, suggested length not more than 500 words - (note: box will expand to fit text)

Research / Project Plan

Scientific Background

Using plain language, describe your approach to the problem suitable for public dissemination.

Limit to 1000 words (note: box will expand to fit text)

Methods

Provide description of methods or specific project plan.

Describe the specific scientific contribution that each collaborator will be making to the project, and their expertise.

Limit to 1500 words - (note: box will expand to fit text)

Specific Goals

Limit to 500 words - (note: box will expand to fit text)

References

(note: box will expand to fit text)

CDER Personnel & Effort

(list all - starting the Project Lead)

Please ensure all appropriate disciplines are included in Project Team

Name	Organization	Position Title	Employee Type	Effort (hr/wk)	Immediate Supervisor
------	--------------	----------------	---------------	----------------	----------------------

<input type="text"/>	Select/Type	<input type="text"/>	Select...	<input type="text"/>	<input type="text"/>
----------------------	-------------	----------------------	-----------	----------------------	----------------------

Non-CDER Collaborators

(list all, if known)

Name	Affiliation	Category	Collaborative Mechanism
------	-------------	----------	-------------------------

http://sharepoint.fda.gov/orgs/CDER-Center-Wide/rsr/_layouts/Print.Form.Server.aspx?XsnLocation=http://shar... 9/22/2014

Budget Details and Justification

NOTE: Prior to requesting books, verify that copies are not available through the FDA library or internal Office collections. All books purchased with RSR funds should be registered with the FDA library on completion of the project.

Budget Category	Item Description	Justification (do not leave blank)	Cost
Select...			

If an unneeded row is added inadvertently please leave

Budget Total
\$0

Special Project Requirements

Does your project involve (Check all that apply)

RIHSC Human Subject, Specimens or data YES NO [Research in Human Subjects](#)

Animals YES NO For information on research involving animals, please contact Rodney Rouse, Chair, White Oak Institutional Animal Care and Use Committee (IACUC) (Rodney.Rouse@fda.hhs.gov)

Will this project involve developing a review tool (e.g., statistical coding, database)? YES NO

Does your project include software development or purchase?
 YES NO

If so, please provide the following information

Approvals
Documenting Approval for your RSR Proposal:
For each RSR proposal, the Project Lead must obtain approval from the following:

- The Project Lead's first and second line supervisor
- Co-Lead(s) (if applicable)
- All collaborators

Supervisory approval is required for all applicants and any participating collaborators. Please attach PDF of approval emails here.

Instructions for converting approval emails:

1. Open approval email
2. Select "Adobe PDF" tab
3. Click 'Convert to Adobe PDF'
4. Save to retrievable location on your computer
5. Upload approval emails using the 'Add Attachments' box above