POLICY AND PROCEDURES

OFFICE OF THE CENTER DIRECTOR

Commitment of CDER Central Funds to Support Intercenter Science Projects

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PURPOSE

This MAPP establishes the policies and procedures for submission, review and approval of science project proposals from collaborating FDA Organizations outside of CDER[1] that require funding by CDER Central Funds[2]. For the purposes of this MAPP, these projects are hereafter referred to as "Intercenter Projects." This MaPP also describes responsibilities of CDER staff in the review, prioritization, approval, and tracking, of Intercenter Projects, and sets expectations for FDA Organizations requesting funding by CDER Central Funds to support Intercenter Projects.

BACKGROUND

CDER scientists engage in a number of scientific collaborations with other FDA Organizations. These collaborations support CDER's regulatory science objectives and enhance the professional development of CDER staff. Where collaborations proposed either by CDER staff or by the collaborating FDA Organization will require transfer via requisition or other mechanism of CDER central funds to the collaborating Center, there is a need for clear policy and procedures for reviewing, prioritizing, approving, and

[1] This includes FDA Centers and organizations within the Office of the Commissioner, including ORA
[2] This MAPP applies only to Intercenter Projects that involve funds from the CDER Central Fund. This MAPP does NOT apply to Intercenter Projects that involve funding from a CDER Office's budget.

tracking Intercenter Project proposals to ensure that they support CDER's science and research priorities.

POLICY

- This MAPP only applies to Intercenter Projects which require funding from CDER's Central account to support the work of a collaborating FDA Organization. It does NOT apply to collaborative projects with FDA Organization directly funded from an approved CDER Office budget
- Each Intercenter Project requiring funding from CDER Central account to a collaborating FDA Organization must be:
    - Described in an Intercenter Project proposal form (Attachment 1)
    - Submitted to the Division of Budget Execution and Resources (DBERM) in CDER's Office of Management for verification of available funds to support the project prior to review
    - Reviewed by appropriate CDER subject matter experts for scientific quality, CDER mission relevance, and potential impact
    - Recommended for funding by the appropriate CDER Office Director or designee[3]
    - Assigned a CDER Project Lead if one has not been identified
    - Reviewed by the CDER Financial Council, and
    - Approved by the CDER Center Director
    - Tracked by the Office of Translational Sciences
- All requests for Central Funds during a given fiscal year must be received by DBERM by March 1
- All requests received by DBERM by March 1 will be reviewed and prioritized in a single yearly review process managed by OTS
- Subsequent review of prioritized proposals by the Financial Council and CDER Center Director will be completed by April 1 and Collaborating FDA Organizations will be notified of funding decisions by April 15
- Funds needed to address immediate and urgent threats to public health and safety may be exempted from the process described in this MAPP

RESPONSIBILITIES

Collaborating FDA Organization

- Approves development of Intercenter Project proposals by FDA Organization staff
- Identifies a single point of contact within their FDA Organization to manage communications and submissions related to all project proposals requiring CDER Central Funds

[3] The CDER Office Director may delegate this decision, but must document concurrence

- Seeks relevant CDER concurrence to ensure Intercenter Project proposal addresses a specific CDER need
- Drafts the project proposal in consultation with the CDER Project Lead (if one has been identified) and completes the Intercenter Project proposal form (Attachment 1)
- Provides oversight for each project and commits to obligating all CDER funds by the end of each fiscal year
- Provides to the CDER Project Lead and OTS IPC an annual progress report and/or a final report for each project supported by CDER Central Funds by Oct 31 of each year

Director, Division of Budget Execution and Resources, CDER Office of Management or designee (DBERM)

- Receives the Intercenter Project proposals from FDA Organizations and confirms the availability of funds in the CDER Central Account
- Sends all proposals received by CDER by March 1 for which funds may be available to OTS IPC for scientific review and prioritization
- Manages the CDER Financial Council and CDER Center Director review of prioritized funding requests/justifications prepared by OTS
- Sends the list of approved Intercenter Project proposals and funding amounts to the collaborating FDA Organization point of contact and to the OTS IPC

OTS Intercenter Project Coordinator (OTS IPC)

- Is appointed by the Office of Translational Sciences
- Manages the scientific review of FDA Organizational proposals forwarded by DBERM
- Collates the scientific review comments and provides prioritized project proposal list to DBERM
- Tracks all funded projects and provides annual summary report on new and ongoing projects to DBERM and CDER leadership

CDER Project Lead (CDER PL):

- For CDER initiated project proposals, after receiving Office Director concurrence, determines the interest of an appropriate collaborating FDA Organization in developing an Intercenter Project proposal
- With supervisory and Office Director concurrence, provides the collaborating FDA Organization with guidance on the scope, goals, and terms of an Intercenter Project proposal to ensure optimization of CDER's investment

- Monitors progress of the Intercenter Project, receives progress or final reports prepared by the collaborating FDA Organization, and forwards to the CDER Office Director and to the OTS IPC
- Updates the CDER science projects database with the approved Intercenter Projects and with annual updates.

CDER Office Director (OD) or designee

- Determines if proposed research collaborations will support the scientific objectives of the CDER Office
- Provides written review, determines priority, and recommends whether each Intercenter Project Proposal should receive CDER funding
- Identifies and/or approves the CDER PL for Intercenter Projects submitted by FDA Organization
- Reviews annual project updates

CDER Financial Council (FC)

- Reviews the Intercenter Project proposals and requests for funds and then makes recommendations to the CDER Center Director

CDER Center Director

- Reviews the Financial Council's recommendations and provides final approval or denial of each funding request associated with an Intercenter Project

PROCEDURES

The Intercenter Project proposal request process can be initiated by a CDER Office or by another FDA Organization. In each case, all Intercenter Project proposal forms from a given FDA Organization (Attachment 1) must be completed and transmitted to CDER/DBERM by a single point of contact representing the collaborating FDA Organization. A flow diagram for this process is captured in Attachment 2.

Proposal Development

- ***Proposal Development – CDER-Initiated Intercenter Projects***
  1. The CDER PL, with supervisory and Office concurrence, may engage directly with a colleague in a collaborating FDA Organization to determine their

interest and ensure concurrence from their management in developing the project proposal

2. If the CDER PL is unable to identify an appropriate collaborator in an FDA Organization, they should request assistance from the OTS IPC
3. The FDA Organization collaborator, in consultation with the CDER PL, completes Intercenter Project proposal form (Attachment 1) for initial review by the collaborating FDA Organization
4. The collaborating FDA Organization submits the Intercenter Project form to CDER/DBERM by March 1 following procedures outlined under *Submission, Review and Approval of Intercenter Project Proposals*, below

- ***Proposal Development - FDA Center-Initiated Intercenter Projects***

1. The FDA Organization drafts the project proposal in consultation with the CDER PL (if one has been identified) and completes the Intercenter Project proposal form (Attachment 1)
2. If the request is to extend an ongoing project, a detailed progress report must be attached to the Intercenter Project proposal form
3. The collaborating FDA Organization, after following its internal review and clearance procedures, submits the Intercenter Project proposal to CDER/DBERM by March 1 following procedures outlined below

Submission, Review and Approval of Intercenter Project Proposals

1. The single point of contact from the collaborating FDA Organizations may submit Intercenter Project proposal forms along with any progress reports to DBERM in Office of Management, CDER on before March 1
2. DBERM determines availability of CDER Central Funds
3. DBERM sends the Intercenter Project proposal forms and statement of available funds to the OTS IPC, who compiles and catalogues all proposals received prior to March 1 and identifies the appropriate CDER Office to review the proposal
4. On March 15, OTS IPC initiates the annual review process by sending the Intercenter Project proposal forms to the appropriate CDER Offices for review and prioritization
5. If CDER OD endorses the proposal, he or she identifies a CDER PL if a CDER PL has not already been identified by the FDA Organization

6. CDER PL negotiates with the collaborating FDA Organization any modifications needed to the scope, goals and terms of the Intercenter Project proposal to ensure optimization of CDER's investment
7. CDER OD or designee provides review, rating and prioritization of the final Intercenter Project proposal to the OTS IPC
8. OTS IPC collates Office Director (or designee) reviews, prioritization and recommendations for all Intercenter Project proposals and sends this information to DBERM
9. DBERM submits the justification, including feedback and funding requests for all Intercenter Projects to the Financial Council
10. The FC reviews the Intercenter Project proposal and justification and then makes a recommendation to the CDER Center Director
11. CDER Center Director reviews the Financial Council's recommendations and provides final approval or denial of the funding request associated with the Intercenter Project
12. DBERM sends a list of approved Intercenter Projects to the FDA Organization IPC and CDER IPC
13. CDER IPC maintains a record of approved Intercenter Projects
14. CDER IPC informs the OD and CDER PL of approved Intercenter Projects
15. The CDER PL receives annual updates on approved Intercenter projects from the collaborating FDA Organization and provides copies to the OD and CDER IPC

SUMMARY OF CHANGES

1. Rev. 1

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
	Initial	N/A

ATTACHMENT 1: Proposal Form

CDER

For technical questions on completing this form contact CDER IPC

Submit by Email | Print Form

CDER IPC Use Only

Commitment of CDER Central Funds to Support Intercenter Science Projects Proposal Form

Please refer to the MAPP 4200.5 when completing this form

Principal Investigator

Last Name | First Name

FDA Center | Division/Office

Project Co-Lead's and Other Study Personnel should be added to the Personnel section on page 3

Project Title

Topic Areas

FDA Strategic Plan for Regulatory Science | CDER Regulated Products | CDER Science Needs

Click on link below for list of topic areas
http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Drugs/ScienceResearch/UCM414050.pdf

Is project currently supported by CDER?

Continuation of Project? ○ YES ○ NO If YES - Title

If proposal builds on results of an ongoing project, you MUST attach a summary of progress.

To attach your report, please
1. Click on paper clip on the lower left.
2. Browse for and select your file.

Progress/Final Report Attached? ○ YES ○ NO

Is project receiving or have you applied for 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

Are you attaching any supplemental information? (i.e., budget justification, progress report, graphs, methods)

○ Yes ○ No

Project Statement

Goal or Impact

Limit to 1-2 paragraphs, suggested length no more than 500 words. *(note: box will expand to fit text)*

Research / Project Plan

Background

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

Methods

- Provide description of methods or specific project plan; for example, include the specific statistical analyses, experimental design, or technology to be used.
- Please also provide scientific contribution and role of each participant.
- Please provide sufficient detail for evaluation by an expert in the field.

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

Specific Goals/Milestones

- Include timelines, expected deliverables, and accomplishments (For multi-year projects, the deliverables for each year must be identified. Continuing projects must make clear for which year funding is being requested).
- Provide length of project
- Limit to 500 words - *(note: box will expand to fit text)*

CDER Personnel & Effort *(list all - starting with Project Lead)*

	Name	Office/Division	Role	Employee Type	Effort (hr/wk)	Immediate Supervisor
Add Row						

If an unneeded row is added inadvertently please leave blank.

FDA Center Collaborators *(list all, if known)*

	Name	Center (e.g CBER,NCTR...)	Center Office	Center Division/Lab
Add Row				

Budget Details and Justification

Please note why item(s) are critical for this project (*Please fill the form below or attach a detail budget document*)

The budget should cover what you are requesting for the fiscal year. Please note that all funds must be obligated in the FY in which they are awarded.

	Budget Category	Item Description	Justification	Cost
Add Row				

If an unneeded row is added inadvertently please leave blank.

Budget Total

Approvals/ Acknowledgements

FDA Center PI Signature		Date	
CDER Project Lead Signature		Date	
Center IPC Signature		Date	
DBERM/Designee Signature		Date	
CDER IPC Signature		Date	
CDER Office Director Signature		Date	
CDER FC Chair Signature		Date	
CDER Center Director Signature		Date	

ATTACHMENT 2: CDER Central funds Workflow