

INFORMATION TECHNOLOGY

Information Management Steering Committee

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PURPOSE

- This MAPP describes the organization and responsibilities of the Information Management Steering Committee (IMSC) and the procedures for bringing issues to the IMSC in the Center for Drug Evaluation and Research (CDER).
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DEFINITIONS

Information Management (IM): The means by which an organization efficiently plans, collects, organizes, uses, controls, disseminates, and disposes of its information, and through which it ensures that the value of that information is fully identified and exploited

Information Technology (IT): The management and implementation of the infrastructure needed to move large quantities of digitized information from one place or person to another, or storing, moving, or making available information through effective viewer and analytical software

IT Project: Any project that involves the use of information technology to develop new or improve upon existing systems that are not solely for individual use. An IT project does not include the creation of new web pages to disseminate information to the public.

MISSION

The Information Management Steering Committee has been established to:

- Evaluate all strategic information management IM needs of CDER staff
 - Evaluate and approve IT policy
 - Approve, prioritize, and monitor resources for strategic information IT projects
 - Facilitate priority IT projects by reviewing status and interceding to resolve issues when necessary
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ORGANIZATION

- The following descriptions and explanations should be applied on a general basis. There will be some fluctuations as necessary given organizational changes and workload demands.

Chair — The IMSC is co-chaired by the Deputy Center Director and the Director, Office of Executive Programs.

Executive Secretary — The co-chairs will designate an Executive Secretary.

Membership — Each of the following organizational units will designate a member or members to represent the program. The organizational unit's director will designate the member.

- Office of Compliance — 1 representative
- Office of Training and Communication — 1 representative
- Office of New Drugs — 2 representatives
- Office of Pharmacoepidemiology and Statistical Science — 1 representative
- Office of Pharmaceutical Science — 2 representatives
- Office of Information Technology — 2 representatives
- Office of Management — 1 representative
- Office of Medical Policy — 1 representative
- Office of Regulatory Policy — 1 representative

Information Management Advisor — The Associate Director for Information Management will serve as a member and advisor to the IMSC on information management and business processes.

POLICIES

- A proposal for a new IT development project must be submitted and approved by the IMSC prior to proceeding with the project. If there is a question as to whether the new IT project needs to be reviewed by the IMSC, the Information Management Advisor should be consulted.
 - This MAPP applies to all IT development except (1) databases/systems strictly for individual use; and (2) the creation of new web pages to disseminate information to the public.
 - No Center resources, financial or personnel, will be devoted to IT proposals that have been denied by the IMSC.
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RESPONSIBILITIES

The Co-Chairs will:

- Manage and maintain the committee and its activities
- Ensure that Center policies on information management are communicated to the IMSC members
- Clear materials (e.g., correspondence, speeches, articles, reports) that represent centerwide IM issues

The Executive Secretary will:

- Arrange and organize IMSC meetings
- Maintain IMSC files (IT proposals, action items and decisions, status reports of IT projects)
- Distribute meeting-related background documents and minutes
- Maintain information about activities of IT-related groups and committees throughout CDER

Members of IMSC will:

- Represent their organizational unit's views on issues under consideration by the IMSC
- Communicate with their organizational unit about the deliberations of the IMSC
- Regularly attend meetings of the IMSC. If a member cannot attend a meeting, an alternate may be designated to attend. (NOTE: A permanent alternate may not be designated.) The alternate must be able to represent the organization and vote in place of the member.
- Develop, facilitate, and monitor progress toward the CDER IT strategic plan
- Deliberate on and recommend action on IT policies
- Provide a forum for discussing and resolving intracenter and intercenter IM issues
- Communicate and promote IMSC decisions to CDER staff and to other interested parties, as appropriate

Project Leads for IT projects will:

- Submit a semiannual report to the Executive Secretary on the status of each project (see Attachment A)
- Notify the Executive Secretary of any new critical issues as they arise
- Respond to additional information requests from the IMSC

OIT (Office of Information Technology) will:

- Provide routine status reports to Agency officials for all OIT-developed IT projects, as required, in collaboration with the Executive Secretary
- Provide information on the status of all OIT projects to the Executive Secretary
- Advise the IMSC on what standards have been established and recommend standards that need to be established
- Advise the IMSC on Agency and Departmental security policies and identify

possible risks in IT proposals

- Provide technical help with IT projects as determined by the IMSC (technical assistance for required OIT support will be defined in a Service Level Agreement developed for each IT project)

The Information Management Advisor will:

- Evaluate and recommend the IT proposals that should be reviewed by the IMSC
 - Facilitate the presentation of IT proposals for evaluation by the IMSC
 - Monitor the status of all IT projects not monitored by OIT
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PROCEDURES

- **IT Proposals and Projects (see Attachment C)**
 1. CDER staff must inform the Information Management Advisor about new IT proposals under consideration for development by completing Attachment B and submitting it electronically to the Executive Secretary. No work on the project can begin before it receives clearance from the IMSC.
 2. The Executive Secretary will initiate tracking of the proposal and immediately forward a copy to the Information Management Advisor.
 3. The Information Management Advisor will review all new IT proposals and recommend those that should be evaluated by the IMSC using the following criteria.

IMSC Recommendation Category	Description	Criteria
High Priority	Recommend for this fiscal year	All of the following: <ul style="list-style-type: none"> ▪ Mandate or urgent ▪ Central to Department, Agency, and Center goals ▪ High business return on investment anticipated
Low Priority	Recommend, as resources permit (Quantify cost, benefit, and risk)	All of the following: <ul style="list-style-type: none"> ▪ Acceptable combination of cost, benefit, and risk ▪ Does not fit one of the other recommendation categories
Reject	Not worthy of implementation (Provide reason)	One or more of the following: <ul style="list-style-type: none"> ▪ Contrary to policy, strategic direction, mission, and/or established standards ▪ Duplicate ▪ Poor combination of cost, benefit, and risk

Other Filter Decisions	Description	Criteria
Additional Information Needed	Requires additional information from the submitter before making IMSC Recommendation (Provide brief description of additional information needed)	Requires additional information of one or more elements described in Attachment B
IMSC Review Not Needed	Does not require review by the IMSC (Provide reason)	<ul style="list-style-type: none"> ▪ Fits within or similar to existing initiative (state which one) ▪ <i>[add other filter criteria as determined by IMSC]</i>

4. After reviewing the IT proposal, the Information Management Advisor will report the recommendations for each proposal to the Executive Secretary within 10 working days of receipt of the proposal.
5. The Executive Secretary will schedule discussion of proposals recommended for IMSC review by the Information Management Advisor for the next available IMSC meeting.
6. IT proposals not recommended for review will be returned to the initiator by

the Executive Secretary within 2 working days of receipt of the information from the Information Management Advisor, with an explanation of why the proposal was not recommended.

7. The IMSC will evaluate any proposals recommended for review and reject, defer, or accept the request based on the following criteria.

Decision	Criteria
<p>Reject Request</p> <p><i>A rejected proposal is not to be pursued unless it is resubmitted for consideration in the future.</i></p>	<p>One or more of the following:</p> <ul style="list-style-type: none"> • Contrary to policy, strategic direction, mission, established standards • Duplicate • Poor combination of cost, benefit, and risk
<p>Defer Request</p> <p><i>A deferred request can be pursued in the future as resources permit. Open requests are automatically reconsidered in the next fiscal year by the IMSC.</i></p>	<p>One or more of the following:</p> <ul style="list-style-type: none"> • Low priority (low urgency) • Marginal cost/benefit ratio • Resource constraints
<p>Accept Request (see below)</p>	<p>One or more of the following:</p> <ul style="list-style-type: none"> • Extension of critical, existing production system • Mandate or Urgent • Supports Department, Agency, and Center Goals • High benefit • Low risk (including technical feasibility, impact on CDER if fails) • Low cost

8. Once a proposal has been accepted, the IMSC will determine whether the project should be (1) OIT Lead, (2) non-OIT Lead, or (3) non-OIT Lead and/or OIT consult according to the following criteria.

Assign To	Criteria	Description
OIT Lead	<ul style="list-style-type: none"> • Central production system and/or operations • Requires significant expertise in CDER infrastructure, technical business processes (resource issue) 	Delegation to OIT as a priority project
Non-OIT Lead	<ul style="list-style-type: none"> • Low risk if fails • Low cost • Nonproduction <i>pilot</i> • Stand-alone (i.e., will not require Help Desk or other OIT support and will not cause disruption to production systems or infrastructure) 	Approval to develop outside OIT with the following caveats: <ul style="list-style-type: none"> • Emphasis on established standards • <i>Pilot</i> status (not centrally supported or protected) • Resource limits established and tracked by Project Lead • Requires minimal to no support from OIT
Non-OIT Lead and/or OIT Consult	<ul style="list-style-type: none"> • Potentially high benefit • Low risk if fails (not a production system and/or operation) • Requires only limited OIT involvement and/or expertise 	Assigned for development outside OIT with the following caveats: <ul style="list-style-type: none"> • Limited OIT technical input, assistance, and review (OIT support and review requirements are defined during the assignment process by the IMSC) • Resource limits established and tracked by Project Lead

9. The IMSC will assign a project lead and an OIT technical advisor to provide guidance on established standards and polices when the project is to be completed outside of OIT.

10. The Executive Secretary will notify all appropriate individuals of the final decision of the IMSC within 2 working days after the decision has been made.

- **Clearance of material such as speeches, articles, and reports**

1. All speeches, articles, reports, or other written material describing policies on information management should be forwarded to the Executive Secretary to obtain clearance.

2. The Executive Secretary will obtain clearance of the material within 10 working days of receipt and will notify the requestor of the clearance and any other comments on the material.

DISPUTE RESOLUTION

CDER staff wishing to contest a recommendation made by the Information Management Advisor can request review of the decision to the Executive Secretary of the IMSC through their program area's IMSC member.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Status Report of IT Project

1. Project Title

2. Project Name

Name and contact information (e-mail, phone)

3. Overall Progress

Briefly review the concept and strategy for the project. Summarize the progress made to date.

4. Milestone Schedule

For each milestone, show the date originally targeted for completion. Also, show the current target completion date and provide a brief explanation if the current and original targets are different.

For example, complete the following table:

Milestone	Original Target Completion Date	Current Target Completion Date	Reason for Variance	Actual Completion Date
Requirements Documented	June 2000	Sept 2000	Took longer than expected to get consensus from the users	
Design Prototype	July 2000	October 2000	Delay in Requirements	
Develop Prototype	August 2000	November 2000	Delay in Requirements	

5. Costs

Show the budgeted and actual amount of costs associated with this project by quarter. Include contract, hardware, software, and any other expenses and provide a brief explanation for each type of expense. Include an explanation for any month where there is a 10 percent or greater variance in budgeted vs. actual costs.

For example, complete the following table:

Cost	Explanation of Cost	1 st Half FY 20__			2 nd Half FY 20__		
		Budget	Actual	Reason for Variance	Budget	Actual	Reason for Variance
Contractor A	Describe Contractor A's role on the project						
Contractor B	Describe Contractor B's role on the project						
Hardware	List the Hardware to be purchased						
FTEs	Describe the role of Center FTE(s)						

	allocated to this project						
Software	List the Software to be Purchased						
Other	List other costs associated with the project						
Total							

6. Issues and Risks

State any known concerns (issues) related to successful completion of this project. Note any problems (risks) that may arise during the course of the effort. Also, describe the impact to the Center of not continuing this effort.

Request for Review of IT Proposal

Title of Proposal:
Sponsoring Office:
Point of Contact:

Date Submitted:

Justification or Objective of Project

1. What is the business need (i.e., what Center strategic goals does this meet)?
2. Is this request a response to a mandate or to a known Center commitment? If so, what?
3. Is this request unique, or are there other known similar needs in the Center?
4. Is this request time sensitive?
5. How will this project support the Center's mission?
6. Who will benefit from this project?
7. How many potential end users are there?
8. What specific outcomes can be achieved with the proposed IT solution that would not otherwise be possible?

Concept and Time Frame

1. State briefly the concept for the IT solution to be used to meet the business need defined in Question 1 above. Include a detailed description and/or diagram of the scope, inputs, outputs, flow of activities, and reports envisioned for the completed project.
2. How will this system improve existing operations?
3. Provide a description of each of the expected end products.
4. What are the target dates expected for the end products?

Issues and Risks

1. What are the known concerns (issues) related to a successful completion of this project?
2. What are the dependencies on other IT systems?
3. What impact will this system have on Center information management plans?
4. What are the long-term and short-term risks and benefits?
5. What is the impact to the Center of not pursuing this effort?

Resources

1. How many FTEs will be required to complete the effort described above?
2. What are the costs associated with known hardware, software, license, or other needs associated with this proposal?
3. What is the anticipated source of the funding (i.e., PDUFA vs. nonPDUFA)?
4. What are the long-term costs associated with maintaining this system? (Include the number of FTEs needed to maintain the system.)
5. What are the projected savings, if any, to the Center if this system is implemented?

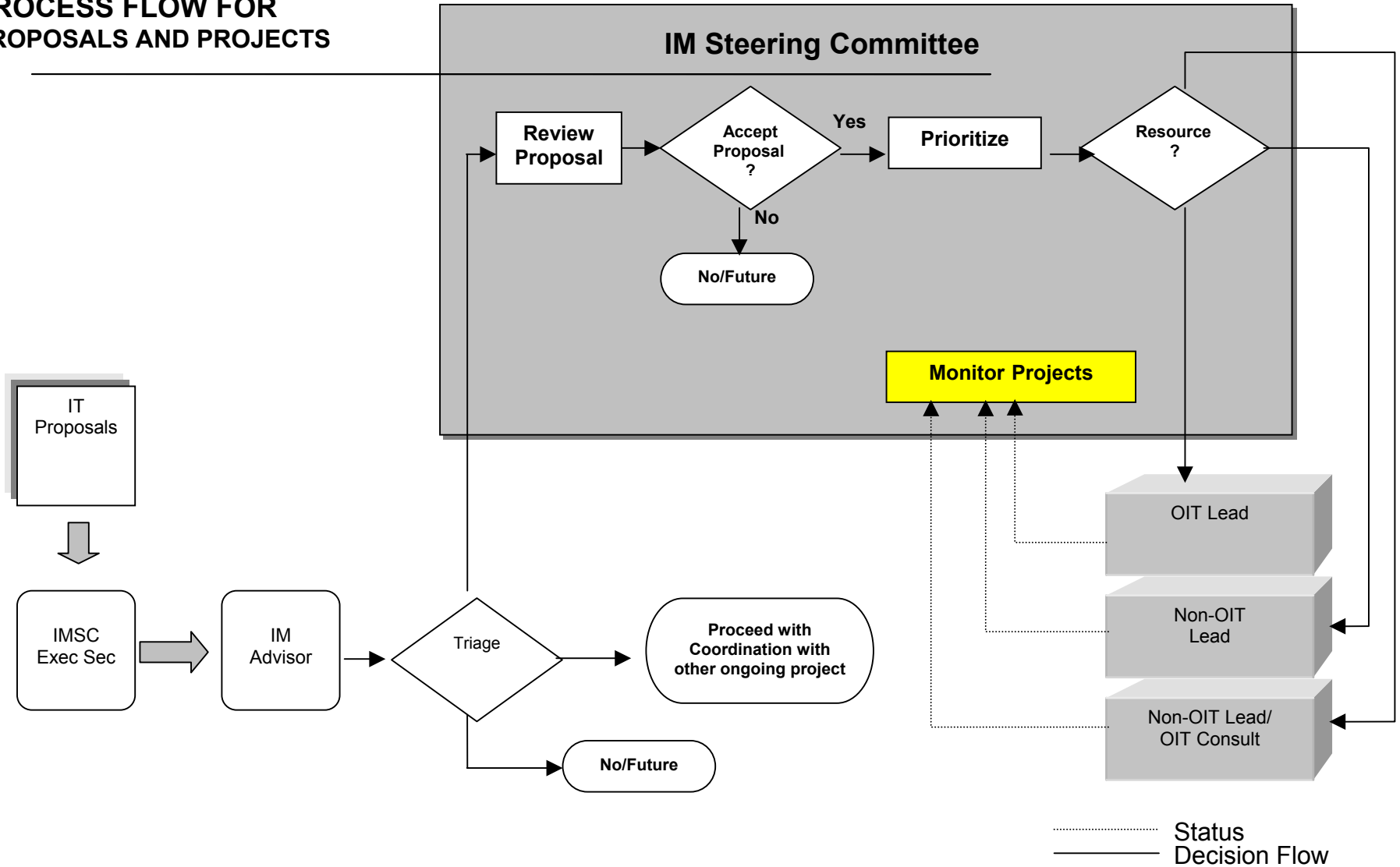
IM Advisor Decision:

Date

IMSC Decision:

Date

**Attachment C
PROCESS FLOW FOR
PROPOSALS AND PROJECTS**



Attachment D

Frequently Asked Questions

Question	Answer	Things to Consider
<i>Where should I submit my "Request for Review of an IT Proposal"</i>	Submit your proposal electronically via e-mail to the Executive Secretary.	
<i>How do I know if I need to submit my proposal for an IT project to the IMSC?</i>	Any IT project to develop a new IT system or database or improve upon existing systems needs to be reviewed by the IMSC, except for the creation of new web pages that disseminate information to the public or systems designed solely for individual use.	If you are unsure if your project needs to be reviewed by the IMSC, you should consult with the Information Management Advisor.
<i>What information should I include in the proposal?</i>	A written proposal. See "Attachment B"	You may be asked to provide a brief presentation at an IMSC meeting summarizing information such as the purpose, scope, and estimated resources.
<i>When should I submit the proposal?</i>	Prior to spending or obligating money or resources. When requested information is known.	
<i>How will requests be tracked?</i>	The Executive Secretary will maintain a list and files of all proposals. CDER staff may request copies of proposals from the Executive Secretary. Committee members can request a proposal be considered if it was not recommended for presentation by the Information Management Advisor.	
<i>Notification/Communication</i>	The Executive Secretary will be responsible for communicating all decisions about an IT proposal to the submitter.	
<i>What happens if my request is not approved by the IMSC?</i>	A rejected proposal is not to be pursued unless it is resubmitted for consideration in the future. No Center resources will be devoted to the project.	A decision may be disputed (see Dispute Resolution section of MAPP).
<i>What can I expect if my request is approved by the IMSC?</i>	Request for periodic status information (at least semiannually), reporting progress on schedule, budget (see Attachment A to MAPP).	