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**POLICY AND PROCEDURES**

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**OFFICE OF STRATEGIC PROGRAMS**

**CDER Informatics Governance Process**

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**PURPOSE**

This MAPP describes CDER’s Informatics Governance policy and procedures. The objective is to align IT investments with overall business priorities, to define decision making authorities, and to assign accountability for executing those decisions.

This MAPP addresses the following FDA mandates, as required by FDA Staff Manual Guide (SMG) 1270.2, *Office of Strategic Programs*:

- Establishes a single center-wide portfolio of informatics initiatives
- Establishes a model for managing all CDER IT priorities, costs and budget, and governance
- Establishes strategic and operational partnerships with internal Clients, service providers, and all other stakeholders

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**BACKGROUND**

As required by the Clinger-Cohen act of 1996, this document establishes policies and procedures for management of IT resources, in compliance with guidance from the Office of

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Management and Budget (OMB), Department of Health and Human Services (HHS), and the Food and Drug Administration (FDA).

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## **POLICY**

CDER's Executive Committee (EC) serves as the strategic decision-making body for CDER's information technology (IT) investments and acts as the Information Technology Investment Review Board (ITIRB), with the advice and counsel of CDER's Program Management Office (PMO). The ITIRB ensures that IT investments are in alignment with CDER's mission, vision, and highest priorities. CDER's Center Director makes the final decisions.

The CDER Informatics Action Plan is the single center-wide portfolio of informatics initiatives. It serves as the basis for resource allocation with FDA's Office of Information Management (OIM), and CDER Offices, and for establishing the CDER Informatics budget. The ITIRB meets on a quarterly basis to review and approve the CDER Informatics Action Plan. Members of the ITIRB serve as Executive Sponsors for each initiative on the CDER Informatics Action Plan.

The Clients, the members of CDER's Executive Committee, decide on the informatics priorities for their respective offices, and communicate these priorities to their assigned Client Managers.

The CDER PMO, which is comprised of the Client Managers, OBI service line directors, and representatives from Office of Information Management, reviews Client requests, provides recommendations, and maintains the CDER Informatics Action Plan.

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## **RESPONSIBILITIES**

### **Center Director**

- Determines members of Executive Committee (Clients)
- Serves as final decision maker

### **CDER Executive Committee**

- Serves as CDER's ITIRB

### **CDER Information Technology Investment Review Board (ITIRB)**

- Meets on a quarterly basis with the OBI director
- Establishes center-wide priorities and resolves conflicts
- Reviews and approves the CDER Informatics Action Plan on a quarterly basis or as needed
- Fulfills capital planning and investment control (CPIC) responsibilities for IT-related activities, per the Clinger-Cohen Act of 1996

- Addresses conflicts in priorities in CDER's Informatics Action Plan

**Director, Office of Strategic Programs (OSP)**

- Serves as signatory on behalf of the ITIRB

**Director, Office of Business Informatics (OSP/OBI)**

- Conducts quarterly reviews of the Informatics Action Plan with the ITIRB
- Appoints Client Managers for each EC member as the single point of accountability to the EC member's office

**Client**

- Defines the processes to identify, assess, and prioritize business informatics needs for their Office
- Presents and discusses informatics needs and priorities with Client Manager
- Participates in the ITIRB
- Ensures Subject Matter Expert (SME) availability for determination of project needs
- Participates in annual Key Element Assessments (KEA) to evaluate OBI's performance

**Client Manager**

- Serves as the single point of accountability for the Client
- Works with the Client to understand their organization's business informatics needs and assesses priority relative to the overall informatics portfolio
- Attends joint business planning meetings with the Client to review project requests and presents project requests to PMO for their assessment and classification
- Performs KEA with the Clients on an annual basis to measure Client satisfaction
- Communicates with director of OBI, the PMO, and PMO Director, and is an advocate for their Clients and Client's needs
- Provides updates on the status of projects, requests, prioritization, issues, etc., to their Clients

**Program Management Office (PMO)**

- Assesses Client requests and makes recommendations on timing, scope, funding, and required resources
- Updates the CDER Informatics Action Plan for final review and approval through the ITIRB

- Recommends projects to be added to the Informatics Action Plan and assigns resources as necessary to work on the project
- Assigns Project Managers (PM) to initiatives on the Informatics Action Plan
- Manages funding, acquisitions, and resource planning to ensure the successful delivery of the approved CDER Informatics Action Plan
- Escalates any major issues to the Clients or to the ITIRB, as appropriate
- Reports to the Director of OBI

**Informatics Program Management Officer (PMO Director)**

- Provides overall guidance and leadership for the CDER Program Management Office, the CDER Informatics Governance Process, and the CDER informatics portfolio and budget

**PMO Manager**

- Manages day-to-day activities of the CDER Program Management Office; facilitates the weekly PMO status meeting with Client Managers, service line Directors, and OIM representatives; leads the initial review of requests; and supports the PMO Director in ensuring the integrity of the governance process and the operational leadership of the CDER PMO
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**PROCEDURES**

Under the CDER informatics governance model, the Office of Business Informatics (OBI) assigns a Client Manager for each CDER Executive Committee member, as the single point of contact for informatics.

**Joint Business Planning**

The Client and the Client Manager conduct joint business planning meetings periodically to review informatics priorities and to discuss project business needs submitted by the Client's organization. The Client Manager consults with the PMO and provides recommendations to the Client.

**PMO Assessment**

The PMO will evaluate the submitted request per the assessment criteria described in this MAPP. If needed, the PMO will assign a business analyst to work with the Client's designee to clarify high level requirements. Based on the assessment, the PMO will recommend a project which will be added to the Informatics Action Plan. The ITIRB will review and approve the Informatics Action Plan on a quarterly basis. The ITIRB will address priority conflicts.

The following criteria will be used to assess all requests:

1. **Strategic Fit** – Does the Client understand and support this request? For example, does the proposal fit the Center/Agency strategic goals?
2. **Redundancy** – Does this request overlap with or duplicate an existing initiative?
3. **Technical feasibility and compliance** – Can this request be done and is this in alignment with existing IT policies and standards (These are owned and governed by OIM and the Center must partner with OIM stakeholders to ensure alignment).

Requests that are not supportive of CDER's long-term strategic goals, redundant with other efforts, or not in compliance with FDA OIM standards will be reevaluated by the Client and Client Manager.

The following criteria will be used to classify all requests:

1. **Impact** – How many users are impacted and does this project touch other IT systems?
2. **Effort** – How many resources and how much time does this project require?
3. **Cost** – What is the total cost to implement and maintain?

Requests that meet the assessment criteria will be added to the CDER Informatics Action Plan. Initial planning will begin for the project to further refine scope, cost, and resource estimates. Timelines will be negotiated in joint business planning based on these estimates. Once approved by the ITIRB, the PMO will assign a Project Manager who submits the Information Technology Investment Management (ITIM) request.

### **Modifications to Existing Projects**

Requests for modifications to existing projects may include continual improvement (CI) requests, enhancement requests, or change requests. Each existing IT system will have a designated business owner and a process for receiving, evaluating, and prioritizing modification requests. The Program Manager and the business owner will be responsible for prioritizing these requests. If the modification request exceeds the original program scope or if there is a priority conflict, the OBI Program Manager will escalate the request to the PMO. The PMO may refer CI requests to joint business planning for prioritization. Requests designated to be implemented will be bundled into scheduled releases and added to the CDER Informatics Action Plan. When the scope of work agreed upon for a project is completed, the project is brought to the PMO for disposition. If it is agreed the project is completed, that project is moved to the “completed” repository on the Informatics Action Plan for future reference.

### **Exceptions**

There are two exceptions to the Joint Business Planning process: Small Project Requests and Grant Funding Applications do not involve the Client for prioritization.

**Exception I: Small Project Requests.** Small project requests require minimal resources, or cost less than \$25,000. Small project requests can be software acquisitions. Small project requests are submitted directly to the PMO using the small project request form, available via the My PMO intranet link on the CDER intranet home page. Small project requests are reviewed by PMO staff to determine if resources or funding are required, and whether a full PMO assessment is necessary. Feedback will be provided to the

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requestor within 15 business days. Requests that meet the assessment criteria can proceed with the ITIM process.

**Exception II: Grant Funding Applications.** Grant funding applications are requests that may need PMO review if they involve IT. The requestor will submit grant funding applications with the Critical Path IT Tools form to the PMO for review. The PMO will review grant funding applications prior to the formal grant funding approval process and provide feedback to the Client within 15 calendar days. The PMO will escalate any major issues or priority conflicts to the respective grant approval committee. Requests that meet the assessment criteria can proceed with the ITIM process. More information on CDER's science and research intramural funding programs can be found on the CDER science and research intranet page.

### **Monitor and Control**

The PMO reviews the Informatics Action Plan weekly to ensure priorities are on track. The Client Managers take issues requiring escalation to the Client for resolution. If the Client and the Client Manager cannot resolve difference of opinion, the issue goes to the ITIRB for resolution, as per MAPP 4151.8, Equal Voice.

Changes to the Informatics Action Plan will be reviewed and approved by the Center ITIRB on a quarterly basis, or as needed.

Client Managers will meet with Clients on a quarterly basis through the process of Joint Business Planning (JBP) to ensure that Clients are keep updated on the progress of their initiatives. These meetings help ensure Clients and Client Managers are in agreement on priorities and project status. Client Managers will also perform a Key Element Assessment (KEA) with each Client on an annual basis to measure Client satisfaction. The Assessment will consist of three elements:

- Collaboration between OBI and the Client,
- Quality of products and services delivered, and
- Timeliness of the delivery for agreed initiatives.

The KEA rating scale is as follows:

10 – Very Good, 8 – Good, 6 – Fair, 4 – Poor, 2 – Very Poor.

Assessment results feed back into continual improvement processes for service delivery.

The Client Managers, as part of their Performance Management Appraisal Plan (PMAP), will be responsible for maintaining and improving Client satisfaction.

### **Capital Planning and Investment Control (CPIC)**

The primary responsibilities of the ITIRB are found in the Clinger-Cohen Act of 1996.

When ITIRB signature is required, the Director, OSP will serve as the signatory, acting on behalf of the ITIRB.

**REFERENCES**

1. OMB, Circular A-130, Revised. Management of Federal Information Resources.
2. Clinger – Cohen Act, 40 USC 1401 et seq., 1996.
3. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.8 Equal Voice: Discipline and Organizational Component.
4. FDA Staff Manual Guide 1270.2, 4/2013, Office of Strategic Programs.
5. FDA Staff Manual Guide 2010.3, 1/2004, FDA Data Standards Council.
6. FDA Staff Manual Guide 3210.2, 8/2004, IT Investment Management.
7. FDA Staff Manual Guide 3210.3, 4/2004, IT Project Management Policy.
8. FDA Staff Manual Guide 3230.2, 6/2004. Enterprise Architecture Policy.
9. FDA Staff Manual Guide 3251.1, 1/2007, Responsibility for Information Security and funding Works with the Center IT Liaison (CITL) to submit the IT Investment Management (ITIM) request and allocate sufficient CDER resources.

**DEFINITIONS**

**Business Informatics** – The discipline of combining various aspects of business management and information technology to ensure that business process needs are represented and met during the development of IT products and systems.

**Business Informatics Needs** – The IT needs of a particular office. Business Informatics needs may include development, purchase, implementation, innovation, or adoption of new technology.

**Business Owner** – The person responsible for identifying and prioritizing business informatics opportunities for an existing IT system, and working closely with the OBI Program Manager to plan and execute continual improvement activities.

**CDER Information Technology Investment Review Board (ITIRB)** – CDER’s IT governance process under the FDA Informatics Governance Board structure. The board’s membership consists of all members of the CDER Executive Committee.

**CDER Informatics Action Plan** – A list of approved IT projects that includes contact information, project description, objectives, measures, status, and schedules. The CDER Informatics Action Plan is available via the My PMO intranet link on the CDER, OSP, and OBI Intranet home pages.

**CDER Informatics Architect** – The person who owns the overall business informatics architecture across CDER and works closely with the FDA OIM Enterprise Architecture Team.

**CDER Program Management Office** – A matrixed staff consisting of the OBI Director, Client Managers, OBI Service Line Directors, a PMO Director, and PMO Manager.

**Capital Planning and Investment Controls (CPIC)** – The Department of Health and Human Services’ (HHS) primary process for making investment decisions, assessing investment process effectiveness, and refining investment related policies and procedures. CPIC is mandated by the Clinger-Cohen Act, which requires agencies to use a disciplined process to acquire, use, maintain, and dispose of IT.

**Client** – The members of CDER’s Executive Committee as identified by CDER’s Center Director.

**Client Manager** – The single point of contact within OBI responsible for representing and managing each Client.

**Continual Improvements (CI)** – Requests for modifications to existing projects. These may also be called CI Requests, Enhancement Requests, or Change Requests. CI Requests may be referred to Joint Business Planning for prioritization.

**Critical Path IT Tools Form** – A form to capture IT needs for projects seeking funding through CDER's Science and Research intramural funding programs.

**Small Project Request Form** – A form to capture IT needs for projects that require minimal resources or cost less than \$25,000.

**Grant Funding Applications** – Applications for funding projects that meet specific criteria defined by the corresponding grant funding approval process.

**Informatics** – The opportunity to explore science, health, and the arts through technology.

**Information Technology Investment Management (ITIM)** – Managed by the Office of Information Management (OIM), the ITIM process standardizes the review, evaluation, approval, prioritization, funding, and implementation of IT products at FDA.

**Information Technology Investment Review Board (ITIRB)** – Comprised of CDER’s Executive Committee, the ITIRB is responsible for resolving priority conflicts and approving the CDER Informatics Action Plan. ITIRB ensures CDER’s IT investments are in alignment with the mission, vision, and highest priorities of the Center.

**Joint Business Planning** – The process of Clients assessing and prioritizing the business informatics needs of their offices with their OBI Client Managers.

**Key Elements Assessment** – Assessment of informatics services performed and completed by the Client and Client Manager in partnership.

**Modification Requests** – A request for new functionality to an existing IT system. Also called Change Requests, Continual Improvement Requests, or Enhancement Requests.

**OBI Service Line Directors** – The OBI Directors representing the following OBI Components:



- Drug Quality and Compliance Services and Solutions
- Regulatory Review and Drug Safety Services and Solutions
- Business Management Services and Solutions
- Data Management Services
- Innovation Management and Architecture Solutions

**Project Requests** – Request for IT efforts from OBI to a Client’s office. Project Requests may include work which requires (a) funding of more than \$25,000, (b) complex planning, (c) resources beyond the requesting office, or (d) involves a large number of users.

**Program Manager** – Designated individual with responsibility for accomplishing program objectives for development, production, and sustainment to meet the user's operational needs.

**SUMMARY OF CHANGES**

Effective Date	Revision Number	Revision
10/25/11	Initial Issuance	n/a
06/06/13	Rev.1	Updated all sections of MAPP to provide further clarification and refinement of procedures based on experience from the date the original version of MAPP 7600.8 became effective. <ul style="list-style-type: none"> <li>• Modified workflow diagrams to provide better clarity of processes.</li> <li>• Added OSP Director to sign on behalf of ITIRB when a signature is necessary and added section on CPIC procedure.</li> <li>• Changed Office name from Office of Planning and Informatics to Office of Strategic Programs.</li> </ul>

**EFFECTIVE DATE**

This MAPP is effective upon date of publication.

**ATTACHMENT 1: Index of Acronyms**

CDER	Center for Drug Evaluation and Research
CI	Continuous Improvement
CITL	Center Information Technology Liaison

**MANUAL OF POLICIES AND PROCEDURES**

**CENTER FOR DRUG EVALUATION AND RESEARCH**

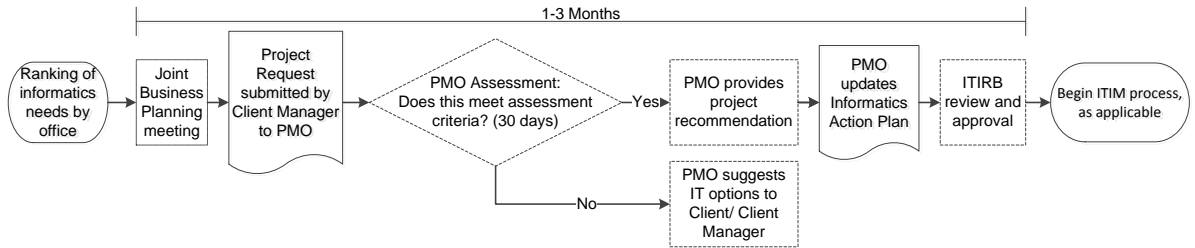
**MAPP 7600.8 Rev. 1**

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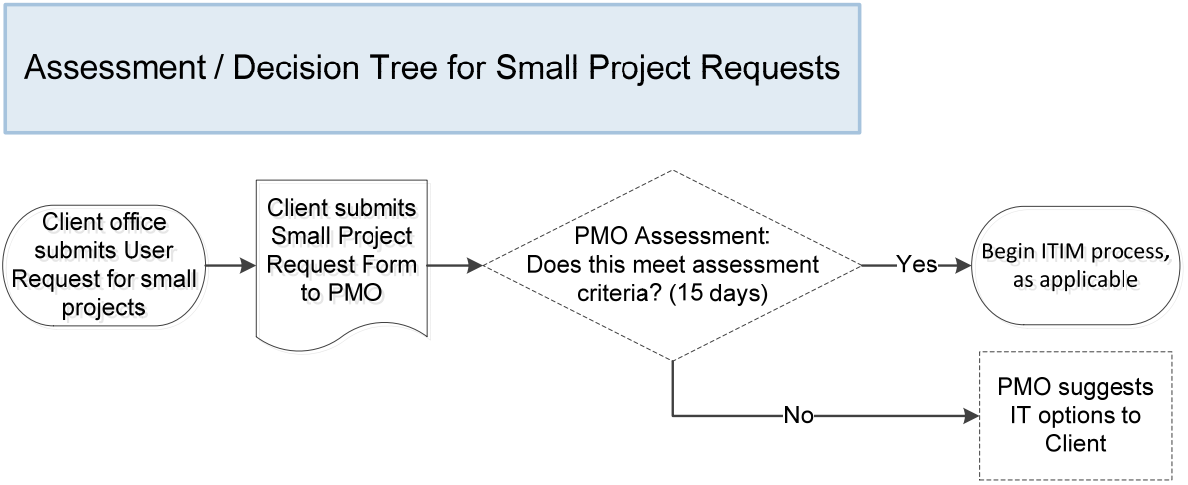
CPIC	Capital Planning and Investment Control
EC	Executive Committee
EPLC	Enterprise Performance Life Cycle
FDA	Food and Drug Administration
HHS	Health and Human Services
IGB	Informatics Governance Board
IT	Information Technology
ITIM	Information Technology Investment Management
ITIRB	Information Technology Investment Review Board
JBP	Joint Business Planning
KEA	Key Element Assessment
MAPP	Manual of Policies and Procedures
OBI	Office of Business Informatics
OIM	Office of Information Management
OMB	Office of Management and Budget
OSP	Office of Strategic Programs
PMAP	Performance Management Appraisal Program
PM	Project Manager
PMO	Program Management Office
SMG	Staff Manual Guide

**ATTACHMENT 2: PMO Assessment: Project Requests**

Assessment / Decision Tree for Project Requests



ATTACHMENT 3: PMO Assessment: Small Project Requests



**ATTACHMENT 4: PMO Assessment: Grant Funding Applications**

