

Office of Foods and Veterinary Medicine

Research Prioritization Framework

Purpose: This document outlines a preliminary OFVM research prioritization timeline and process to support the FDA Foods and Veterinary Medicine Program Strategic Plan. This document also provides initial thoughts on implementation, tracking progress, and assessing the impact of our research objectives and associated projects in the operational fiscal year (FY), to coincide with planning for the upcoming fiscal year(s). Horizon-scanning and planning for research programs is intended to occur one or two years in advance.

The following terminology and sequence will be used in outlining this framework:

Strategic Goal/Outcome ⇒ Knowledge Gap ⇒ Research Objective (RO) ⇒ Projects/Studies

Operational Year (FY-XX)

1. Start of New Research Objectives and Associated Projects

- Execution of the plan finalized at the end of the previous FY. Research objectives (RO) designed to address knowledge gaps seen as barriers to attaining strategic goals. The RO's to be undertaken within the operational FY are identified during the annual research prioritization cycle.
- Individual CARTS projects are assigned to each RO to address the needs of the RO (if a project is multi-year, it should be phased yearly with defined milestones). For each research objective, a road map should be determined that outlines specific projects with associated resources, timelines, and milestones for coordination, implementation, and completion. Research objectives that are determined to be cross-cutting are to be reviewed by the appropriate research coordination group (RCG) in determining the road map for implementation.
- Research objectives that are determined to be Center/ ORA-specific would also require a road map. However, those would be managed and tracked at the Center/ ORA-level, with periodic updates on progress.
- Timeframe: October 1 would be the earliest starting time for new research objectives and associated projects. Some projects could begin after October 1, but ideally prior to December 31.
- This timeframe does not preclude the development/initiation of new ROs at any time during the Operational Year to address unforeseen issues that are deemed emergency or mission-critical in nature. These new ROs should be implemented, coordinated, and tracked with the appropriate RCG.

2. Tri-annual Review of Research Objectives and Associated Projects

- Evaluation of both cross-cutting and Center/ORAs-specific research objectives and associated projects, to include a discussion of projects that are experiencing delays or that are discontinued (all such studies should have a Study Status Analysis form completed in coordination with the applicable RCG).

- A look at the impact of RO's and associated studies will also be conducted during the Tri-annual Review to track the range of impact/outcomes of completed RO's and their associated projects. This process is detailed in step 3.
- Timeframes:
 - December: Update on the progress of implementation of studies in CARTS; also to include a retrospective look at the prior year research objectives and associated projects, status of ROs being carried over from the previous FY, and update on close out status for completed ROs.
 - April: To be coordinated with Mid-Year Review that is both an evaluation of current FY research objectives and forecasting for next FY, see below; introductions of new studies to address current RO.
 - July: A comprehensive evaluation of the current state of the operational year research objectives and associated projects; Center/ORa/CORE updates on upcoming RO prioritization, including close-outs and carry overs; RCG pre-evaluation of cross-cutting ROs for the next FY.

3. Impact of Research Objectives and Associated Studies*

- A comprehensive look at completed research objectives (~2 years) and their associated projects on public health using the FVM Research Impact Framework as a reference.
- Eventually, this will also include looking at active and upcoming research objectives/studies to help facilitate the impact of research findings.
- 6-8 weeks prior to the Tri-annual Review meeting: Impact chairperson pulls a list of studies that are due for follow-up. RCG's and impact chairperson/Project Manager collect data on research objectives, cross-cutting studies and center-specific studies for outcomes and impacts that have already been realized and that are still evolving. Each research objective/study is then flagged for future follow-up based on the findings of this inquiry. Data is entered into a spreadsheet that is created by the impact chairperson.
- Results are presented and discussed at the Tri-annual Review, and a sub-sample of research objectives/studies is selected for further impact analysis to be conducted by the impact workgroup.
- Timeframe: April, July, December; the focus of the tri-annual meeting will depend on data collection and program needs. Therefore, the impact focus of each tri-annual meeting will vary.

*The processes and procedures for this component of the research prioritization framework are still being developed. Details are subject to change.

4. Mid-year Review of Research Objectives and Associated Projects

- Inclusive of all the retrospective assessments as noted in the tri-annual review above, with the added forward looking perspective in planning for the next FY.
- Horizon scanning -- A forward look at possible strategies and research needs 18 months in the future in preparation for subsequent fiscal years (two FY in the future).
- A forward look at methods validation and implementation needs for the next FY.

- Encourage attendance by Center and ORA senior science leadership.
- Timeframe: April; 3-4 hours in duration in anticipation of expanded agenda.

Planning Year for (FY-XX + 1)

1. Gap Analysis and Activity Planning

- The budget formulation process is a series of activities that begins two years in advance of a given fiscal year.
- Determination of risk-informed FY priorities (Office of Research Planning and Strategic Management; OFVM Risk Analytics Team). Integrating prioritized hazard-commodity pairings into the research ranking process.
 - Timeframe: October - January
- Align to FVM Strategic Objectives and provide to Centers, CORE and ORA.
- Activity Plan: functional groups defined by their regulatory focus (e.g., Policy, Research, Compliance) evaluate the resources required to fill identified gaps and improve public health impact.
- Timeframe: January-April, annual planning process.

2. Work/Spend Planning

- No later than June, the Center/Office program staff should begin reviewing the budget spend plan for the upcoming fiscal year that was filled out during the formulation process.
- OFVM, along with the Center/Office of Management, will begin meeting with program staff to begin clarifying the funding requirements necessary for the upcoming fiscal year.
- No later than the third week in September, the spend plans will be presented to the Deputy Commissioner for Foods and Veterinary Medicine for review and final approval.
- Timeframe: May - August

3. Center, ORA and CORE Prioritization Meetings

- Identification of Knowledge Gaps to address Research Objectives based on risk-informed FY-XX needs.
- Each organizational unit will conduct their coordinated processes for identification of research needs in preparation for the joint FVM Program prioritization meeting (see below).
- Each organizational unit will begin the process of developing a road map for implementing the new research objectives (road maps for potentially cross-cutting research objectives should be coordinated with an associated RCG).
- Timeframe: May through mid-June

4. Joint FVM Program Prioritization Meeting

- Follows the Center, CORE and ORA prioritization to align both Center-specific and cross-cutting needs.

- Research Objectives are verified as Center-specific or cross-cutting and assigned to RCGs for tracking and managing.
- Timeframe: August

5. Governance Board approval of FY-XX Strategic Objectives/Research Objectives

- In late August, the spend plans will be presented to the Governance Board for review. In early September, any requested changes by the Governance Board will be made to the spend plans. The timeline for finalizing the spend plans will be dependent on when the Deputy Commissioner for Foods and Veterinary would like to review the spend plans.
- Timeframe: August/September

6. Research Objective Road Maps

- This will have to be defined for each research objective (pending approval of the spend plan.)
- Research objectives that are determined to be cross-cutting or Center/ORAspecific will require a road map for implementation.
 - Timeframe: Mid-June - September
- CARTS: New Projects are entered into CARTS and linked to new research objectives. Approval of projects will be routed through the appropriate Center-and ORA-processes.
- Begin to map projects to address the research objectives (ROs)

FVM Research Prioritization Timeline

