

Food and Veterinary Medicine (FVM) Science and Research Steering Committee (SRSC) Charter

1. Purpose

This charter establishes the FDA Foods and Veterinary Medicine (FVM) Science and Research Steering Committee (SRSC) and sets forth its mission, membership, authority and the roles and responsibilities of key Stakeholders.

2. Mission of the FVM SRSC

The FVM SRSC is the operational arm of the FVM Executive Council in the area of science and research. As such, the FVM SRSC's primary role is to lead, coordinate, and unify natural science research and methods development strategies across FVM. Key components of the mission include:

- Developing and implementing an FVM Science and Research Strategic Plan to strengthen and maintain core science and research capabilities;
- Developing and implementing a common framework and process for prioritizing FVM research;
- Developing and implementing a unified analytical methods development and validation program that is aligned with FVM priorities;
- Developing and communicating improved processes for technology transfer of research and methods to FVM program offices;
- Aligning the roles and responsibilities of each laboratory operating unit across FVM; and
- Optimizing use of laboratory staff and resources across FVM.

3. FVM SRSC Membership

The membership of the FVM SRSC is determined by the FVM Executive Council and includes science and research leaders from the operating units of the FVM Directorate [the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM)], the foods and veterinary medicine operations of the Office of Regulatory Affairs (ORA), the National Center for Toxicological Research (NCTR), the Office of International Programs (OIP), and the Office of the Chief Scientist (OCS) in the Office of the Commissioner. Members of the FVM SRSC play a dual role as representatives of their organizations *and* as leaders in this critical FVM initiative whose success depends on close collaboration and addressing issues from a cross-cutting perspective. This leadership role will be a significant duty for FVM SRSC members requiring support from their respective organizations' senior management.

The FVM SRSC will be chaired by the Office of Foods and Veterinary Medicine (OFVM) Chief Science Officer/Research Director. The Vice-Chair will be the OFVM Senior Science Advisor.

The FVM SRSC core membership will be composed of science and research leaders from OFVM, CFSAN, CVM, and ORA, with representation from NCTR, OCS and OIP.

Primary Members

Primary Members	
Role	Title
Chair, OFVM Member	OFVM Chief Science Officer/Research Director
Vice-Chair, OFVM Member	OFVM Senior Science Advisor
CFSAN Member	CFSAN Senior Science Advisor
CFSAN Member	CFSAN, Director Office of Regulatory Science
CFSAN Member	CFSAN, Director Office of Applied Research and Safety Assessment
CVM Member	CVM, Deputy Director for Science Policy
CVM Member	CVM, Director Office of Research
ORA Member	ORA, Director Office of Regulatory Science
ORA Member	ORA, Director Food and Feed Scientific Staff
ORA Member	ORA, Member of the ORA Scientific Advisory Council
NCTR Member	NCTR, Associate Director for Research
OCS Member	OCS Designee
OIP Member	OIP, Senior Advisor for Scientific International Affairs

Staffing

A Project Manager will be assigned to the OFVM SRSC Chair and Vice-Chair to provide essential support in moving the work of the FVM SRSC forward to completion. Project Manager(s), and other supporting staff, will participate in FVM SRSC meetings in a non-voting status.

Ad Hoc Membership and Subject Matter Experts (SMEs)

The FVM SRSC may designate advisory individuals with specific interests or expertise to attend meetings, or may appoint ad hoc members to help with specific issues. SMEs will also participate in a non-voting status.

The FVM SRSC may establish subcommittees to facilitate progress on particular projects, such as formulation of methods development and validation plans. The FVM SRSC Chair approves subcommittee membership in consultation with other FVM SRSC members and the FVM Executive Council. Subcommittees will have a limited lifetime, adjourning when their tasks have been completed; however, standing subcommittees may also be appointed if needed. Subcommittees will present their reports and recommendations to the FVM SRSC for discussion. The FVM SRSC Chair and Vice-Chair will communicate the recommendations and decisions of the FVM SRSC to the FVM Executive Council and, as appropriate, to the FVM Governance Board.

4. Authority of the FVM SRSC

The FVM SRSC has full authority to design and oversee implementation of the cross-cutting planning and decision-making processes needed to achieve its mission and to integrate scientific programs across the operating units of FVM (CFSAN and CVM), along with the foods and veterinary medicine operations of ORA, as well as ensuring the involvement of appropriate line management. As it deems appropriate, the FVM SRSC is authorized to evaluate new and ongoing scientific and research projects for mission relevance, scientific rigor, progress toward goals, potential for leveraging other resources, and opportunities for technology transfer. The FVM SRSC will seek input from appropriate federal partners, e.g., Center for Disease Control and U.S. Department of Agriculture, state partners, industry, and

academia when appropriate to inform decision-making. The FVM SRSC will facilitate FVM Executive Council involvement and decision-making, and that of the FVM Governance Board as appropriate, through regular reports on its activities and significant issues the FVM SRSC is addressing.

Conflict Resolution

Information and recommendations from the FVM SRSC to the FVM Executive Council, and potentially the FVM Governance Board, are expected to reflect the needs, interests and thoughts of all members. Decisions on critical issues will be accomplished through a consensus decision-making process to the greatest extent possible. If consensus is not possible, the Chair will seek to resolve differences and propose resolutions that all members can accept. Issues that cannot be resolved on that basis will be presented, with majority and dissenting views, to the Food and Veterinary Medicine Executive Council for decision.

5. Roles and Responsibilities

FVM SRSC Chair:

- Reviews advance information provided prior to FVM SRSC meetings. Provide clarifying questions on advance information to information providers as needed;
- Identifies SMEs as needed to support agenda and gain their attendance;
- Approves or denies recommendations for SME participation from the other Primary Members;
- Notifies Primary Members of decisions; and
- Designates the FVM SRSC Vice-Chair as Chair *pro tem* if unable to participate in a scheduled FVM SRSC meeting.

FVM SRSC Vice-Chair:

- Serves as the FVM SRSC Chair *pro tem* if the Chair is unable to participate in a scheduled FVM SRSC meeting.

Primary Members:

- Review advance information provided prior to FVM SRSC meetings to include receiving pre-briefs from SMEs as appropriate;
- Provide clarifying questions on advance information to the Chair as needed;
- Based upon review of the meeting agenda, are prepared to recommend to the Chair; and additional SMEs that FVM would benefit from having in attendance in a non-voting status.
- Based upon decisions reached by the FVM SRSC, participate in:
 - The identification of responsibility for actions;
 - The determination of the appropriate oversight method(s) in conjunction with Center or ORA line management to ensure implementation of agreed upon actions; and
 - Notifying the Chair if unable to participate and designate a proxy, ensuring proxy can represent Primary Member position as appropriate.

FVM Executive Secretariat:

- Participates in FVM SRSC meetings in a non-voting status;
- Ensures the distribution of an agenda and action items to the FVM SRSC prior to each meeting; and

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- Posts minutes from each meeting on the FVM Intranet homepage or SharePoint site and distributes to all FVM SRSC members, including agreed upon action items and issues requiring escalation to the FVM Executive Council.

Individuals or Teams Bringing Business Before the FVM SRSC:

- Provide the FVM Executive Secretariat with any presentation materials 2 working days prior to an FVM SRSC meeting;
- Provide answers to clarifying questions to the Chair within 48 hours (2 working days);
- Are prepared to pre-brief Primary Members in advance of meeting execution as required; and
- Focus discussion on obtaining decisions, guidance, and/or assistance from the FVM SRSC to include any additional authorities and/or resources that will be required to execute assigned tasks.

6. Coordinating Instructions

Budget/Resources

The FVM SRSC will outline the budget and other resources needed to accomplish its missions. This may include recommendations to invest funds for research coordination, instrumentation purchases, expert consultation, information technologies, and contract work. The Chair and Vice-Chair of the FVM SRSC will consult with the FVM Executive Council as well as ORA Senior leadership on budget and/or human resource requirements.

Meetings

The FVM SRSC will hold meetings monthly and additionally as required. Quorum for FVM SRSC meetings will consist of at least six Primary Members able to attend and at least one representative from each FVM operating unit (CFSAN and CVM) and ORA. The FVM SRSC can agree, during the meeting, to extend the allotted time for an agenda item, if necessary. The agenda for the next meeting will be discussed at the end of the current meeting, including discussion of follow up action items. The Project Manager will be responsible for ensuring the distribution of an agenda and a list of action items to the FVM SRSC prior to each meeting. Minutes from each meeting will be posted on the FVM Intranet homepage or SharePoint site and distributed within three (3) days of the meeting to all FVM SRSC members, including agreed upon action items and issues requiring escalation to the FVM Executive Council.

Members are encouraged to participate in person; however, other two-way, interactive communications means deemed acceptable by the FVM SRSC Chair, such as conference calls or video teleconference, may be used.

7. Duration

The FVM SRSC Charter remains in effect until revoked or amended.

8. Changes

Recommended changes to the FVM SRSC Charter may be initiated by Primary Members or by the FVM Executive Council or FVM Governance Board. Any proposed changes shall be documented by the FVM SRSC Support Staff and receive a 66 percent or higher concurrence from the Primary Members prior to being offered to the FVM Governance Board for final approval.

9. Approval

This Charter is approved by the Deputy Commissioner, Foods and Veterinary Medicine. The FVM Director, Executive Secretariat Staff is responsible for retaining a copy of the Charter. The FVM SRSC Project Manager is responsible for updating the Charter as change requirements are met, and disseminating updated Charters to the Director, Executive Secretariat, Primary Members and other Stakeholders as required.

APPROVED BY:

/s/

7/30/14

*Erik Mettler, Associate Commissioner, OFVM/
Co-Chair, FVM Executive Council*

Date

/s/

7/29/14

*Jennifer Devine, Associate Commissioner, GO/
Co-Chair, FVM Executive Council*

Date

Appendix A. Specific FVM SRSC Goals

Science and research activities are ever-present throughout FVM and are essential to the Program's success. The Operating units of FVM (CFSAN and CVM), along with the foods and veterinary medicine operations of ORA, each have significant scientific resources, including subject matter experts, specialized laboratories, and methods development capacity. To make the best use of these resources and capacities and fulfill the FVM vision for science and research, the FVM SRSC is charged with the following activities and responsibilities:

A. Developing, implementing and revising, as needed, an **FVM Science and Research Strategic Plan**. This will include:

- Reviewing the science strategic plans of CFSAN, CVM, and ORA to assess alignment with FVM goals and priorities, including:
 - i. Assessing current capabilities and capacity to meet FVM business needs and science/research goals; and
 - ii. Assessing the capacity of current IT systems to uniformly identify and monitor science/research activities among the FVM operating units (CFSAN and CVM), along with the foods and veterinary medicine operations of ORA).
- Developing a unified FVM Science and Research Strategic Plan to:
 - i. Better align and utilize existing capabilities;
 - ii. Establish core research capabilities that are current with state-of-the-art;
 - iii. Direct research to fill data gaps and meet program/business needs;
 - iv. Dedicate skills and support for scientific computing needs;
 - v. Establish the IT systems needed to support integrated planning and implementation of the science and research program; and
 - vi. Optimize use of both internal and external resources.
- Coordinating and integrating FVM science and research activities with other ongoing FDA-related initiatives, e.g., FDA's Strategic Plan for Regulatory Science.

B. Developing and implementing a **common framework and process for prioritizing FVM research**. This will include:

- Designing and overseeing implementation of a annual process for prioritizing investments in FVM research, to include:
 - i. Seeking iterative input from Program Offices within the operating units of FVM to prioritize public health risks;
 - ii. Conducting needs assessments utilizing an inclusive, well-defined analytical tool and decision process that can be used to link FVM business needs with research requirements and prioritize research activity on that basis; and
 - iii. Identifying FDA laboratories of excellence in specific research areas and defining roles and responsibilities for these and all laboratories in the FVM operating units to:
 - 1. Enhance, encourage and facilitate collaborative research and reduce research redundancy;
 - 2. Assist with allocation of resources;

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3. Promote communication and collaboration between operating units; and
 4. Increase transparency of decisions.
- Overseeing the annual evaluation of and recommendations for improving FVM science and research efforts through the following activities:
 - i. Annual updates;
 - ii. Periodic reviews of resources to address gaps across FVM;
 - iii. Organization and individual professional development, including:
 1. Incentives to reward cross organizational collaborations, e.g. multiple Centers or Center(s) and ORA; and
 2. Maintaining and enhancing staff expertise through regular training.
 - iv. Development of FVM-related science forums/seminars to:
 1. Showcase ongoing and completed scientific studies;
 2. Provide opportunities for FDA scientists to network in order to collaboratively advance the FVM science strategic plan; and
 3. Function as a conduit for ideas/concerns from working-level scientists to the FVM Executive Council and FVM Governance Board.
- C. Developing and implementing a **unified analytical methods development and validation program** aligned with the operational program needs of FVM. This will include:
- Reviewing current methods development and validation activities across CFSAN, CVM, ORA, and NCTR where applicable;
 - Ensuring that method development priorities align with FVM and FDA Regulatory Science strategic plans and redirecting efforts that do not align;
 - Designing an integrated program for methods development and validation, including:
 - i. A process for prioritizing current and future FDA method development needs based on the operational program needs of FVM;
 - ii. Exploring opportunities for innovative methods research to take advantage of new technologies and techniques that can improve program efficiency and effectiveness;
 - iii. Assigning work and recommending allocation of resources based on established priorities to Center and ORA line management;
 - iv. Creating specific methods development and validation subgroups and developing clear expectations for collaborative behavior and work output;
 - v. Defining methods validation and verification criteria; and
 - vi. Ensuring timely transfer of new methods and best practices to field laboratories and, as appropriate, Federal, State and local partners as well as global and private industry partners.
- D. Developing and communicating **improved processes for technology transfer of research and methods** to Program Offices within the operating units of FVM. This will include:
- Engaging FVM operating unit Science and Program Offices as early as possible to prioritize efforts to meet the most critical program needs, based on:
 - i. Shared understanding of program requests and priorities; and
 - ii. An effective collaborative prioritization process.

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- Developing performance and outcome measures to assess the success of the research and science programs in meeting FVM mission objectives.