

Guidance for FDA Staff

THE LEVERAGING HANDBOOK

An Agency Resource for Effective Collaborations

FINAL GUIDANCE

Additional copies are available from:

*Dockets Management Branch
Food & Drug Administration
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852*

<http://www.fda.gov/oc/leveraging/handbook.pdf>

Text version: <http://www.fda.gov/oc/leveraging/handbook.html>

Mail: the Voice Information System at 800-835-4709 or 301-827-1800

For questions regarding the content of this document, contact Dano B. Murphy (301) 827-0801.

**U.S. Department of Health and Human Services
Food and Drug Administration
February 2003
Corrected June 2003**

Guidance for FDA Staff

THE LEVERAGING HANDBOOK

An Agency Resource for Effective Collaborations

NOTE: This guidance document is being revised to correct inadvertent errors in the guidance dated February 2003 as follows:

- In Chapter 4, section C.3.c., "Office of Human Resources Management/Ethics and Personnel Security Branch" was revised to "Ethics and Integrity Branch/Division of Management Programs".
- In Appendix C, section 3.d., "HHS" was revised to "FDA", and in section 3.i., new item "v. The payment is for 'light' refreshments as defined in 41 CFR § 301-74.11" was added to the list.
- In Appendix D, section 10, "March 20, 1995" was revised to "August 8, 2002", and "Special Counsel for Ethics" was revised to "Designated Agency Ethics Official".
- In Appendix E, section 1.b., "substantially" was revised to "significantly" in the last sentence.

**U.S. Department of Health and Human Services
Food and Drug Administration
February 2003
Corrected June 2003**

TABLE OF CONTENTS

Chapter 1 – Introduction	1
A. Background	2
B. Agency Leaders Identify the Need to Emphasize Leveraging	2
C. Purpose of this Handbook.....	2
Chapter 2 – Quick Start for Leveraging	4
A. Frequently Asked Questions (FAQs).....	4
B. Getting Started.....	9
C. Contacts for FDA Leveraged Collaborations	9
Chapter 3 – The Leveraging Process	10
A. Preliminary Steps for Developing Leveraged Projects.....	11
B. Formalizing the Agreement	13
C. Implementing Projects and Learning From Leveraging	15
Chapter 4 – Leveraging Mechanisms	17
A. Overview Of Leveraging Mechanisms	17
B. The Partner Is A Non-Government Entity	18
C. The Partner Is A Government Entity.....	20
Chapter 5 – Legal and Ethical Points to Consider	22
A. Introduction	22
B. Does the Leveraging Arrangement Involve a Gift to the Agency or an Augmentation of Appropriations?	23
C. Does the Proposed Leveraging Arrangement Involve Delegation of Agency Authority?	25
D. Does the Proposed Leveraging Arrangement Present Potential Institutional Conflicts of Interest or Other Ethical Concerns?	26
E. Would the Proposed Leveraging Arrangement Involve Co-Sponsorship?.....	30
F. Should the Proposed Leveraging Arrangement be Accomplished Through Notice and Comment Rulemaking?	30
G. Would Federal Advisory Committee Act (FACA) Procedures Apply to the Proposed Activity?	31
H. Will the Proposed Leveraging Activity Involve Intellectual Property Issues?	32
Chapter 6 – Internal Review and Sign-off	34
A. “Risk-Based” Review of Proposed Leveraging Projects.....	34

Appendix A - Suggested Leveraging Concept Worksheet	36
Appendix B - Checklist for Outside Leveraging -- Ethical Concerns.....	37
Appendix C - Basic Principles of Co-Sponsorship.....	38
Appendix D - Model Co-Sponsorship Agreement.....	46
Appendix E - Relevant Statutes	48
Appendix F - Charter for Leveraging Consultant Council	50

Guidance for FDA Staff¹

THE LEVERAGING HANDBOOK

An Agency Resource for Effective Collaborations

This guidance represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Chapter 1 – Introduction

Leveraging consists of partnerships, cooperative agreements, or any similar collaborative arrangement that is entered into by FDA and another organization, such as a corporation, educational institution, trade or consumer group, government agency, or foreign government. Leveraging is always cooperative and beneficial to all the parties involved, and advances FDA's mission to protect and promote the Nation's public health.

This Handbook is a compendium of information and tools to support leveraging. It was developed for Agency staff and managers who may be involved in leveraging project development and implementation. It is intended to provide the reader with an introduction to and an overview of key leveraging topics and issues. This guidance finalizes the draft guidance of the same title dated November 2001.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by the Leveraging Task Force, an intra-agency work group assembled by the Office of the Commissioner, Food and Drug Administration.

A. Background

The technology and science used to evaluate the status of the Nation's public health and to devise remedies for identified problems is constantly becoming more complex and sophisticated. Often, traditional solutions are no longer adequate to address all the critical dimensions of the problems. At the same time, most government and private organizations world-wide are being pressured by stakeholders and shareholders to deliver better results within tighter budget margins. Leveraging has been identified by FDA's leadership as a critical long-term strategy that can achieve the Agency's goal of protecting and promoting the Nation's public health consistent with the need for greater operating efficiencies.

B. Agency Leaders Identify the Need to Emphasize Leveraging

The value of and the need for further leveraging has been underlined by FDA leaders in both internal communiqués and in presentations to external audiences and have included:

- FDA's mission to protect and promote the public health is not ours alone,
- academia, health providers, other government agencies, regulated industry, and consumers all have roles to play in advancing the public health,
- leveraging, collaboration, cooperation, or partnering are not new to the Agency,
- resources from outside organizations and individuals that have shared interests have helped FDA accomplish its vital mission in the past and these efforts are on-going and will expand in the future,
- cooperative leveraging ventures are a means to maximize our intellect, time, money, and resources,
- FDA, at all levels of the organization, should think of leveraging and other collaborative opportunities as primary strategies for achieving our mission.

Leveraged collaborative work helps FDA's limited resources to go further, and reaps the benefits of a wide range of experience, expertise, and energy from the greater scientific community, while maintaining appropriate oversight of our legal and regulatory obligations.

C. Purpose of this Handbook

Use of the information in this document will help support consistency in Agency leveraging. It will be especially useful in the development of leveraging arrangements with external organizations and agencies and the creation of new leveraging mechanisms and arrangements, but it will also be of value to Agency

personnel contemplating the use of proven mechanisms and arrangements for conducting leveraged collaborations.

The chapters that follow describe how to establish a leveraged collaboration, what should be considered before, during and after implementing a project, and suggestions for managing legal and ethical issues.

- Chapter 2 – Quick Start for Leveraging - presents an informative question and answer section that should help those new to leveraging become quickly acquainted with leveraging concepts and processes. The chapter also contains help for getting started.
- Chapter 3 – The Leveraging Process - provides an overview of basic steps in the process of leveraging, focusing on arrangements with outside organizations. The chapter addresses general issues related to the process of qualifying, negotiating with, and collaborating with others to achieve FDA goals.
- Chapter 4 – Leveraging Mechanisms - addresses concerns about controls and resource commitments, by providing an overview of existing contractual and financing mechanisms that can be used for leveraging.
- Chapter 5 – Legal and Ethical Points to Consider - addresses legal issues and ethical concerns regarding actual and perceived conflicts of interest.
- Chapter 6 – Internal Review and Sign-off - presents a process for the review of leveraging proposals and sign-off of leveraging projects.

Appendices Documents and information referenced in the Handbook or that would be useful to implementing a leveraged collaboration.

- Appendix A Suggested Leveraging Concept Worksheet
- Appendix B Checklist for Outside Leveraging -- Ethical Concerns
- Appendix C Basic Principles of Co-Sponsorship
- Appendix D Model Co-Sponsorship Agreement
- Appendix E Relevant Statutes
- Appendix F Charter for Leveraging Consultant Panel

Chapter 2 – Quick Start for Leveraging

This chapter contains three sections, answers to frequently asked questions (Section A), tips on getting started and finding useful information (Section B), and who in FDA can help you implement a leveraged collaboration (Section C).

A. Frequently Asked Questions (FAQs)

1. What is leveraging?

Leveraging is the creation of collaborative relationships or formal agreements with others outside FDA. The collaborations may develop as partnerships, cooperative agreements, or other similar arrangements entered into by a component of FDA and another organization, such as a corporation, educational institution, trade or consumer group, government agency, or foreign government. Leveraging is always cooperative and beneficial to all the parties involved, and is structured to advance FDA's mission to protect and promote the Nation's public health.

2. What are the benefits of leveraging?

Leveraging creates initiatives through which FDA and its collaborators share resources to achieve goals that neither party could achieve on its own or that could be achieved better as a collaboration. Through leveraging, the Agency can reap the benefits of a wide range of experience, expertise and energy from the scientific and public health communities, while maintaining appropriate oversight of our legal and regulatory obligations. Examples of reaching goals through synergism include joint workshops to assess particular public health challenges, co-sponsored training sessions, consensus standard setting, mission-related research, and others.

3. What resources are shared in leveraging?

Resources contributed by either FDA or other parties could consist of expertise, product or regulatory experience, equipment, facilities, reagents, support staff and services, funding, or any other intellectual or physical resource.

4. Why would FDA participate in leveraging?

FDA would use a leveraged collaboration to address an important aspect of its public health mission that the Agency could not do alone or that could be performed better through a collaboration. The benefits of leveraging are mutual. Parties would collaborate to gain access to the valuable resources possessed by the other party that would enhance the ability of both to reach a desired goal. Resources that might be leveraged are numerous, but typical examples would be expertise, equipment, emerging technologies, and databases.

5. Why would other parties participate in leveraging with FDA?

For many of the same reasons FDA would. FDA might possess scientific knowledge that industry would value. The collaborator might want to participate in creating training programs for FDA staff and stakeholders, or evaluating emerging public health concerns, or utilizing diagnostic or therapeutic advances developed by FDA scientists.

6. When did FDA begin leveraging?

FDA has worked with outside groups for decades. In the early 1970's, under Commissioner Edwards, FDA expanded its use of outside advisory committees to harness the knowledge of experts outside the Agency to maximize the quality of certain product reviews.

7. Why leverage now?

FDA's operating environment is becoming more and more interconnected with other stakeholders. The scientific issues that FDA addresses continually increase in complexity and the answers are often dependent on the use of the latest technologies, which may not be immediately available within the Agency. FDA's internal resources may not always be adequate to address all of the critical dimensions of the multitude of emerging public health issues. At the same time, FDA and its governmental counterparts world-wide are being pressed by stakeholders to deliver better regulatory oversight within tighter budget margins. FDA leadership has identified leveraging as a critical long-term strategy for meeting these and other challenges to our ability to achieve our public health mission.

8. What is the purpose of the Leveraging Workgroup?

The Leveraging Workgroup, which is composed of senior FDA staff and managers, began meeting in September 1999 to examine all aspects of leveraging and to ensure that leveraging is promoted as a way of accomplishing the Agency's mission while providing oversight of the policies and mechanisms used to implement leveraged collaborations.

9. What is the Leveraging Consultant Panel?

The Leveraging Consultant Panel was formed to provide senior-level agency encouragement and support to the leveraging goals of the Centers, ORA, and the Office of the Commissioner. Members of the Leveraging Consultant Panel are high-level agency managers, including Center Directors, Deputy Center Directors and the Chief Counsel. The Panel serves a problem solving function and addresses novel or sensitive leveraging issues. The Panel may also

suggest ways to eliminate as many barriers to leveraging as is legally and ethically prudent.

10. How is FDA building its leveraging infrastructure?

FDA is building leveraging into the Agency's infrastructure by including leveraging strategies in its budget and strategic plans, developing a leveraging data base, convening forums in which to share leveraging experiences, maintaining leveraging Intranet and Internet sites, creating a handbook for implementing leveraging proposals, and establishing Agency Leveraging Contacts and a Leveraging Consultant Panel to address novel or sensitive issues.

11. How does FDA communicate leveraging information?

FDA communicates information about leveraging activities and developments by incorporating the leveraging message into agency speeches, articles and other routine external communications, delivering the leveraging message at the spring stakeholder meetings, and incorporating leveraging into FDAMA reports.

12. Do other agencies leverage?

FDA is fortunate to have a wealth of leveraging expertise to draw on from an Interagency Regulatory Reinvention Forum (Forum) that FDA initiated, along with two other regulatory agencies, EPA and OSHA, in 1996. Under the leadership of FDA/ORA, the Forum grew to include more than twenty agencies from 1996 to the present. The Forum uses information obtained from a survey of seven regulatory agencies to gain insight into how other agencies perceive and practice leveraging.

The following are examples of how other agencies use leveraging to combine resources and achieve desired outcomes through a coordinated effort:

- U.S. Customs leverages with the Immigration and Naturalization Service in their Border Coordination Initiative to increase cooperation and mission performance on the Southwest border. U.S. Customs, in their Compliance Measurement Program, leverages with the import trade community to assess where improvement in regulations, policies, and procedures are needed and to target industry sectors that need to improve their levels of compliance.
- The Department of Agriculture partners with public and private organizations to address challenges in program delivery. Examples of these efforts include ways to deliver crop insurance programs through private crop insurance companies and ways to use state and county agencies to implement federally funded programs and research grants.

- The Occupational and Safety Health Administration promotes work site health and safety programs by working with firms to find the best solutions to problems in the workplace.
- The Department of Transportation partners with various industry and government interests, such as pipeline operators, to develop risk management models.

13. What are examples of FDA leveraged collaborations?

FDA began carrying out leveraging activities in the 1970's. These activities have been very beneficial and have been continued over time. During the 1990's, FDA expanded its leveraging partnerships to include the following examples:

- In May 1991, FDA established the National Center for Food Safety and Technology (Moffett Center), FDA's first government/academia/industry collaboration, which has proven to be a valuable asset, providing critical scientific information and expertise in food processing and packaging technologies to enhance the safety of food.
- JIFSAN, a multidisciplinary research and education partnership with the University of Maryland, works in the areas of risk analysis, applied nutrition, microbial pathogens and toxins, and animal health sciences. The goal of JIFSAN is to provide an environment in which the private and public sectors can pool resources and ideas to improve the scientific bases of public health policy.
- The Mammography Quality Standards Act provided a framework for FDA to work with private and state accreditation bodies to ensure that mammography facilities meet FDA quality standards. The agency certifies private and state bodies to accredit mammography facilities and contracts with state health agencies to carry out inspections of mammography facilities.
- The Center for Drug Evaluation and Research, in association with the nonprofit Product Quality Research Institute, promotes research on improving drug manufacturing, such as drug blending processes, which may support science-based regulatory policy.
- FDA's National Center for Toxicological Research has many collaborative programs with other agencies, industry, and academia that leverage outside scientific expertise - including research projects to develop bioassays for assessing the toxicity of regulated products.
- In the Take Time to Care network, FDA works with over 80 national organizations, including regulated industry, senior citizen groups, associations, and other government agencies to deliver its message of safe

medication use to over 1.5 million people throughout the nation by means of more than 1000 interactive annual events.

14. Won't collaborations with regulated stakeholders pose serious questions of conflict of interest when FDA becomes both the collaborator and the regulator?

Yes, it is possible that some proposed collaborations with regulated stakeholders could pose potential conflicts. However, as discussed below, this does not mean that all leveraging projects with regulated stakeholders must be avoided. In many cases careful planning, with the help of the guidance in the Leveraging Handbook, will result in the agency successfully pursuing leveraging projects with regulated stakeholders. In other cases the difficulties will be too great to overcome and the agency will decide that those projects are not appropriate to undertake. Each project must be approached and evaluated thoroughly and thoughtfully.

A challenging aspect of leveraging is that in some cases the agency will need to learn how to function effectively as regulator and partner at the same time. Leveraging with regulated stakeholders may pose difficult issues, and that is one reason the Handbook contains discussions and checklists of important practical, legal, and ethical principles to consider, as well as expert contacts to consult, in deciding whether a particular project is appropriate for the agency to undertake. In this regard, Chapter 3 of the Handbook, "The Leveraging Process," and Chapter 5, "Legal and Ethical Points to Consider," are particularly helpful.

15. Why were the stakeholder meetings held?

FDA held two public meetings to discuss ways in which FDA can better leverage its resources by working with outside organizations, such as academia, consumer groups, scientific experts, industry, public health providers, states and other government agencies. The meetings were held March 23, 2000, at Stanford University and April 12, 2000, at Duke University. Over 300 people attended the meetings and over 25 leveraging proposals were presented to the agency. FDA is in the process of reviewing the proposals to determine if any of them are appropriate for the Agency to undertake. To review the transcripts of the meetings, please visit the FDA Dockets Management website at <http://www.fda.gov/ohrms/dockets/dockets/00n0001/00n0001.htm>.

B. Getting Started

1. What does the Leveraging Handbook contain and who should use it?

The Leveraging Handbook is a compendium of information and tools that can be used to initiate and support leveraged collaborations. It was developed for use by agency staff and managers who may want to develop and implement leveraged projects.

2. Who at FDA can participate in leveraging?

You can. The leveraging tool should be considered a primary resource by everyone in the Agency regardless of their, or their organization's, responsibilities.

3. Can someone in FDA help me to find a collaborator?

FDA employees are encouraged to identify potential partners. FDA's Leveraging Contacts can also help you locate potential partners, identify possible programmatic areas that could benefit from leveraging, and assist with the mechanics of setting up a collaboration. How to obtain the list of Leveraging Contacts is provided below in section C.

4. Will supervisors and management support my leveraging project?

Leveraging activities have also been made an element of every FDA SES performance plan to ensure that the promotion and implementation of leveraged collaborations will be supported by top management on down. Support, however, does not mean automatic approval of any leveraging project you might suggest. All leveraging, in addition to conforming to the legal and ethical constraints described in Chapter 5, should be consistent with Agency strategic priorities and policies.

C. Contacts for FDA Leveraged Collaborations

The Leveraging Contact assigned to your Center or Office can help you with issues that are not sufficiently covered by this document. These individuals can be located at: <http://www.fda.gov/oc/leveraging/levcontacts.htm>. Additional information can be obtained via the INTERNET at the Office of Facilities, Central Acquisitions, and Services (OFACS) site: <http://www.fda.gov/oc/ofacs/partnership/techtran/1stpg.htm>.

Stakeholders interested in leveraging with FDA should contact the Leveraging Contact in the Center or Office that deals with the products or technology that would be the subject of the potential collaboration.

Chapter 3 – The Leveraging Process

The purpose of this chapter is to provide a suggested step-by-step template to help Agency personnel who are contemplating leveraging or who would like to become more familiar with the process. The chapter can also serve as a reference because it directs the reader to more detailed sources of information. Some are included in this Handbook as appendices.

The steps identified below have been grouped into 3 general phases:

A. Preliminary Steps for Developing Leveraged Projects

This phase involves the identification of a public health challenge that may be addressed by FDA as a leveraged collaboration. The section takes the reader through the early stages of formulating approaches to the issue, identifying the Agency's goals, the resources needed, and potential collaborators.

B. Formalizing the Leveraging Agreement

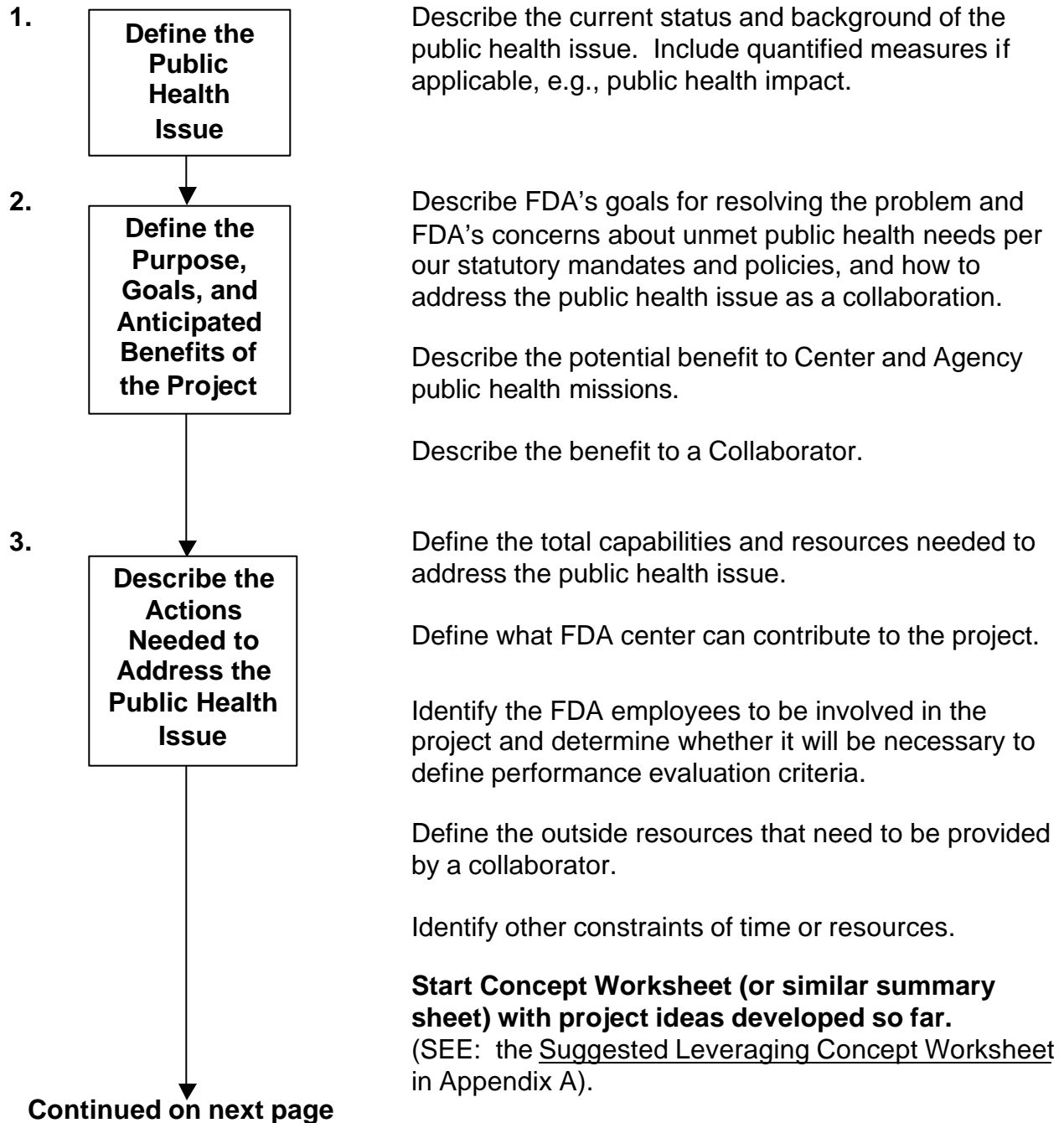
This phase deals with how to finalize preliminary negotiations between FDA and a collaborator.

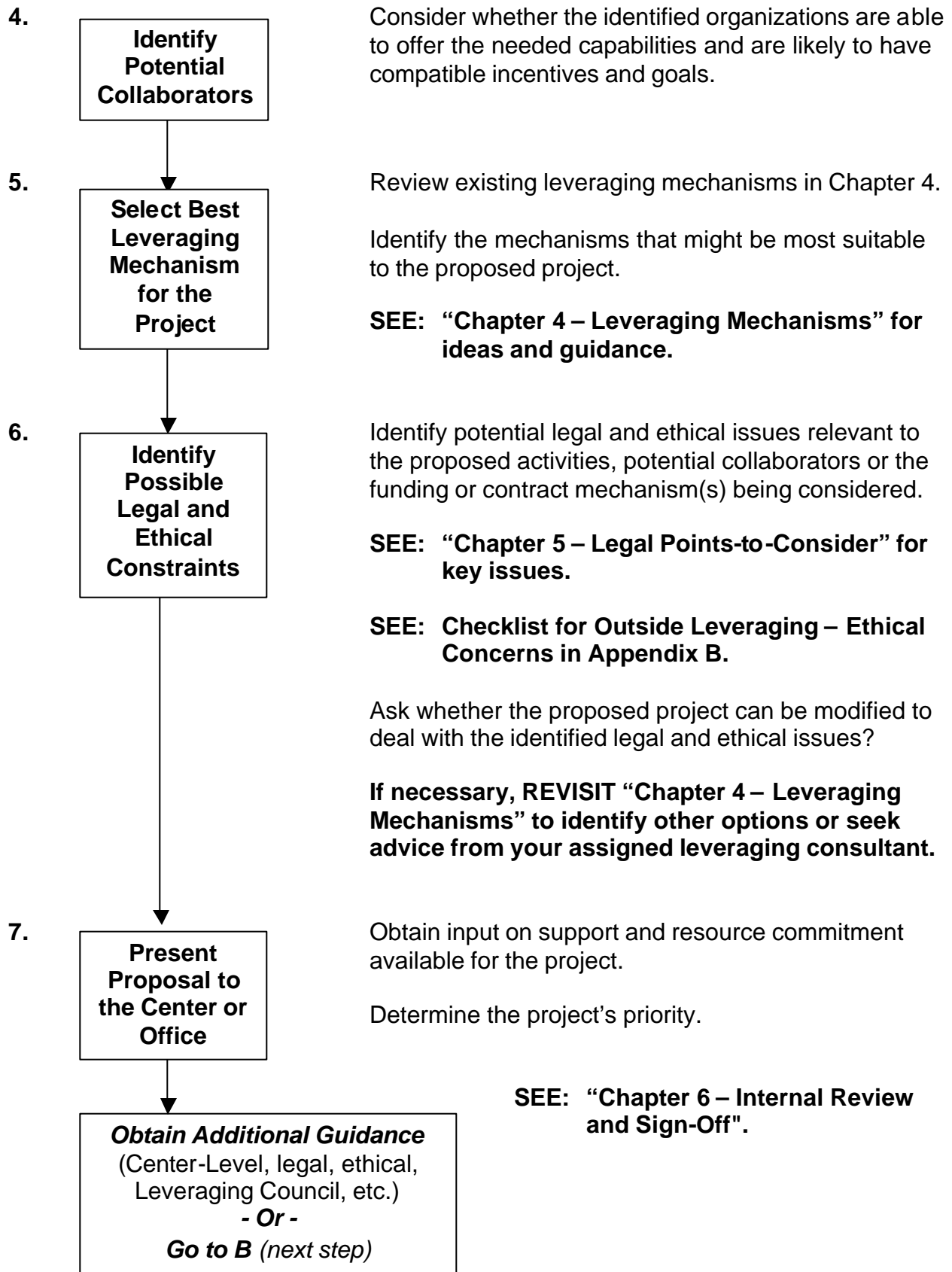
C. Implementing Projects and Learning From Leveraging

This phase describes the collaborative relationship from the time of implementation to the completion or termination of the project. It also includes factors to consider when assessing the success of the project and the effectiveness of the mechanism used.

A. Preliminary Steps for Developing Leveraged Projects

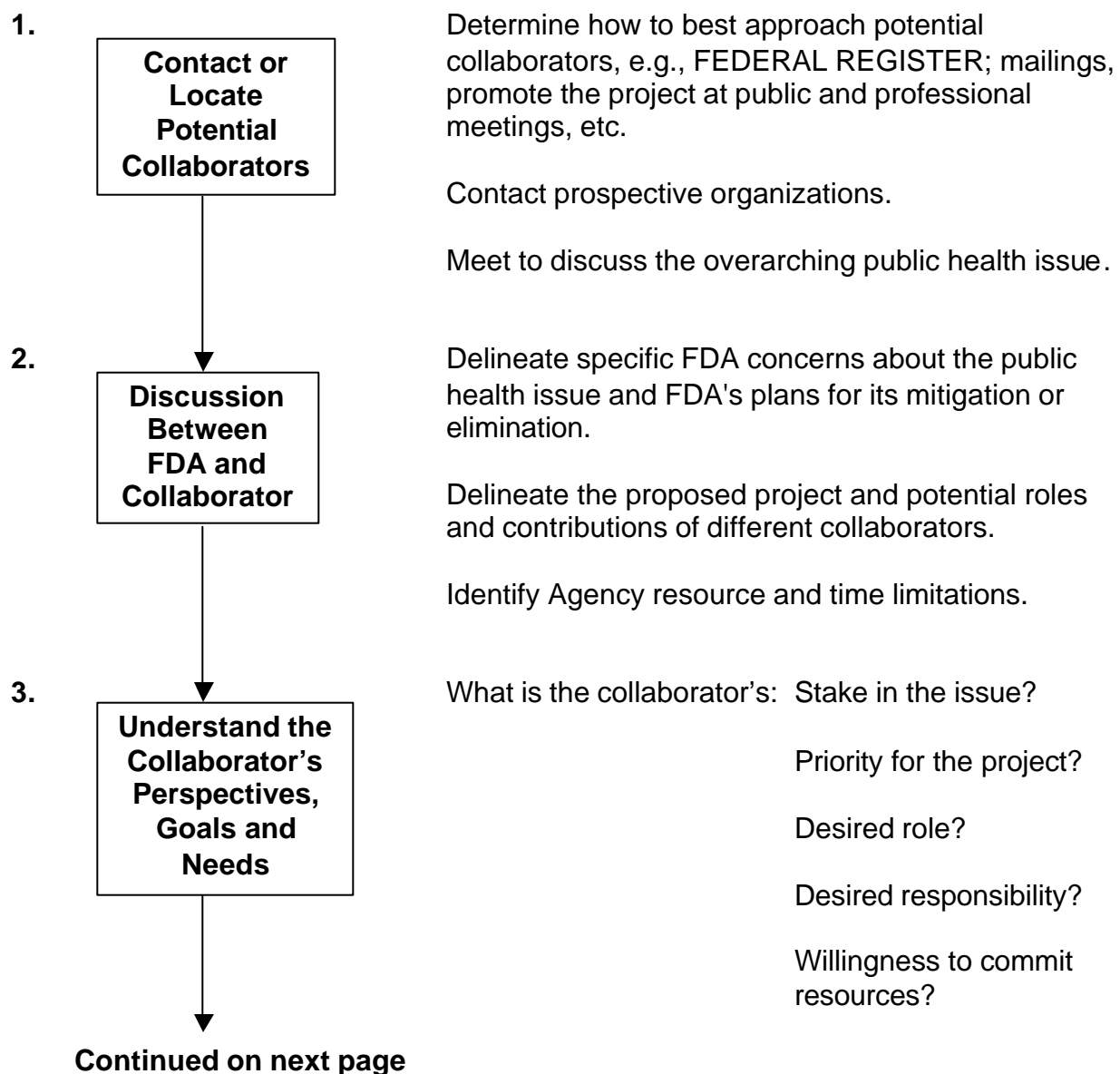
Leveraging efforts will typically start with informal exploratory discussions, brainstorming, and other forms of creative idea generation and problem solving. These activities, conducted by FDA staff, may include individuals from other concerned organizations. In practice, personnel pursuing leveraging may vary the sequence of the outlined steps and different projects will require different time periods for the discussions. A suggested approach for developing leveraged projects is presented below.





B. Formalizing the Agreement

After completing the preliminary discussions, staff can proceed to formalize the agreement between FDA and the prospective collaborator(s). Written agreements should be developed between non-FDA organizations and other Departmental agencies to ensure a clear understanding of the performance roles and responsibilities. This phase of leveraging recognizes that “the devil is in the details”; and what is specified in the formal agreement will often be critical to getting the results desired. It should also be recognized that the necessary discussions can take time and will require the support (and sometimes the active involvement) of Center or Agency management. A suggested approach for formalizing leveraged collaboration is presented below.



3 cont'd.

Understand the Collaborator's Perspectives, Goals and Needs

When can the collaborator begin the work?

For what time period will it commit needed resources?

Does the collaborator have goals for the project that are not part of FDA's agenda?

Note any other concerns and caveats that come up for FDA or the prospective collaborator.

4.

Review Prospects - Determine the Best Collaborative Arrangement

Review discussions held with prospective collaborators with Agency colleagues and managers.

Assess factors for success for each potential collaborator including:

Can needed resources or expertise be delivered?

Are the conflict of interest issues manageable?

Is a good working relationship likely?

5.

Negotiate the Leveraging Agreement With the Collaborator(s)

Draft the specific roles and responsibilities for FDA and collaborator, include:

Resources and expertise to be provided.

The total budget, include collaborator's funds.

Activities to be performed or delivered by each Party.

Activities not to be performed.

Establish timelines and milestones.

Describe duties and draft performance evaluation criteria for bargaining unit employees.

Points of communication and coordination.

6.

Begin Work Or Go to C. (below)

C. Implementing Projects and Learning From Leveraging

Depending on the type of leveraging project, the following general process may apply. It is presented with the usual caveat that every project is somewhat unique and the order and applicability of any one of the following steps may vary in the context of a particular project.

1.

**Create Plans
for the Project**

Write work plans, which should include:

Specific tasks for each party.

Assign the tasks to FDA or the collaborator.

Establish timelines for the completion of intermediate tasks (milestones).

Set a schedule for communication with other collaborators so that the work can be coordinated and progress can be monitored.

2.

**Perform the
Work and
Document
Progress**

Conduct tasks assigned to FDA.

Meet or talk with collaborators as needed or as described in the plans.

Record milestones, results, and accomplishments.

Prepare written reports.

3.

**Communicate
Results –
Promote
Successes**

Publish results of the project in appropriate forums, e.g., journals, trade publications, conferences, etc.

Use Office of Public Affairs to promote successful initiatives to the public and interested stakeholders.

4.

**Submit a Final
Report**

Describe results and accomplishments achieved with collaborator.

Continued on next page

5.

Evaluate the Leveraging Project

Use staff evaluations, documentation, and recorded data to assess the advantages and disadvantages of the particular leveraging experience.

If applicable, prepare written evaluations of bargaining unit employees and recommend appropriate action.

In evaluating the project consider such factors as:

The leveraging activity per se.

Budget issues.

The collaborator.

The leveraging mechanism used.

The quality of communication.

The quality of management oversight.

Other factors.

6.

Lessons Learned

Prepare recommendations for future leveraged projects based on lessons learned from the completed collaboration.

7.

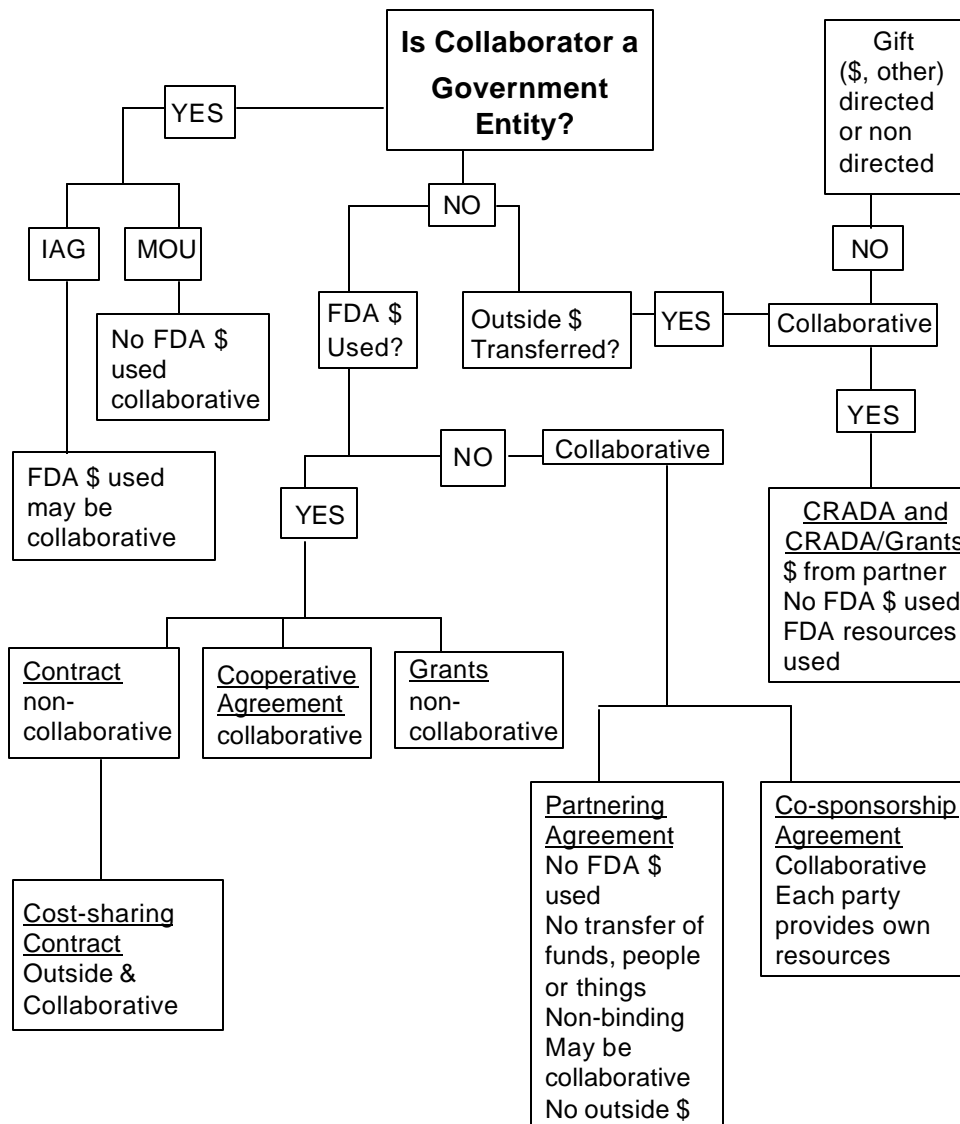
Change the Process per the Findings

Use reports and findings from the previous steps to implement changes where needed.

Chapter 4 – Leveraging Mechanisms

A range of contractual and financial mechanisms can be used to leverage. Selection of the best mechanism often depends on the collaborator, whether FDA funds are to be committed, and whether intellectual property rights may arise from collaboration. The schematic below provides an overview of defined mechanisms that would be appropriate for most leveraged collaborations. The text that follows defines terms and describes when each mechanism is used.

A. Overview Of Leveraging Mechanisms



B. The Partner Is A Non-Government Entity

1. Federal Dollars are Provided

a. Cooperative Agreement

Involves collaborative effort between the FDA and the recipient in which substantial programmatic involvement is anticipated between the FDA and the recipient during the performance of the activity. The recipient, through the existing process, applies for funds from the Federal source inviting applications.

b. Grant

The grantee (organizational entity), through the existing review process with the Center and Office of Facilities, Acquisitions, and Central Services (OFACS), applies for grant funds from the FDA. The FDA provides money to the grantee in order to accomplish a public purpose of support and stimulation; there is no substantial involvement between the FDA and the grantee during the performance of the financially assisted activity. The grantee is responsible and accountable both for the use of the funds provided and for the performance of the grant-supported project or activities.

2. Federal Dollars are Awarded

a. Cost Sharing Contract

Relationship between the FDA and a non-Federal source (nonprofit educational institutions or other nonprofit organizations) in which the Federal Government purchases goods or services for its use. Potential collaborators compete on the basis of technical merit and other factors for one specific award. In this arrangement, the collaborator receives no fee and agrees to absorb a portion of the costs, in the expectation of compensating benefits.

b. Contract

Arms-length formal relationship between the FDA and a non-Federal source in which the Federal Government acquires, by purchase or lease, goods or services for the direct benefit of the Federal Government. Contracts are awarded on a competitive basis through a process that considers technical merit and other factors.

3. No Federal Dollars are Contributed

a. Cooperative Research and Development Agreement (CRADA)

Involves collaborative efforts with one or more partners (academia, industry, not-for-profit, for-profit, state and local government organizations) to further develop FDA technology, inventions, training programs, etc. The CRADA partner may provide funds to be used for CRADA project costs; FDA and the partner may each contribute staff time and expertise, equipment, supplies and facilities. Both parties are expected to make significant intellectual contributions to the project which should be mission-related and a priority for the Agency.

For further information go to:

<http://www.fda.gov/oc/ofacs/partnership/techtran/crada.doc>

<http://www.fda.gov/oc/ofacs/partnership/techtran/crada.pdf>

4. FDA Receives Funds from the Partner

a. CRADA/Grant

Following the existing process and with the Center Director's approval, the FDA employee applies for grant funds from non-Federal sources in the amount of \$10,000 or more. The purpose of the grant application, i.e., obtaining funding support for a particular research project, should be consistent with FDA's research priorities and meet the grant application criteria. FDA receives the funds by entering into a "funds only CRADA." OFACS would review and process the approved grants.

For further information go to:

<http://www.fda.gov/oc/ofacs/partnership/techtran/crada.doc>

<http://www.fda.gov/oc/ofacs/partnership/techtran/crada.pdf>

C. The Partner Is A Government Entity

1. FDA Receives Funds from a Government Partner with Grant Authority

a. Grant/Inter-Agency Agreement (IAG)

Following the existing process and with the Center Director's approval and OFACS review, the FDA employee applies for grant funds from Federal sources inviting applications. When possible, FDA enters into an Inter-Agency Agreement with the awarding organization to receive the funds.

2. Funds are Either Received or Provided by FDA

a. Interagency Agreement (IAG)

Involves collaborative efforts with other Federal agencies whenever collaborations for the purpose of sharing knowledge, personnel or other resources would strengthen programs of mutual concern in the public interest, extend overall consumer protection through use of the collective resources, or eliminate overlapping or duplication of effort. This agreement involves FDA providing or receiving a transfer of funds, provision of services, loan of staff, use of property, facilities or equipment, or exchange of information.

For more detailed information on the above mechanisms see:

<http://www.fda.gov/oc/ofacs/partnership/techtran/1stpg.htm>

3. Funds are Neither Received nor Provided by FDA

a. Memorandum of Agreement (MOU)

May involve collaborative efforts with non-Government entities; FDA does not provide or receive funds or real property. This is considered a general understanding which may be formally implemented by another mechanism (e.g., Cooperative Agreement).

b. Gift Fund Authority (Directed and non-Directed)

Involves the acceptance of money, but not real property. FDA has authority to accept gifts in its institutional capacity; such gifts are not intended to benefit individual employees but are intended to aid or facilitate the programs or operations of the Agency itself.

c. Co-Sponsorship Agreement with outside entity

Joint development of a conference, seminar, symposium, educational program, public information campaign, or similar event related to the mission of the Agency. Involves FDA and one or more non-Federal entities that share a mutual interest in the subject matter. Each party provides its own resources.

For additional information, consult your Leveraging Contact found at <http://www.fda.gov/oc/leveraging/levcontacts.htm>. Other useful information can also be obtained from the Ethics and Integrity Branch/Division of Management Programs, Office of Financial Management, and Office of Chief Counsel.

Chapter 5 – Legal and Ethical Points to Consider

A. Introduction

Effective partnerships with Federal and non-Federal entities can further consumer protection through the sharing of data, expertise, and unique research resources; enhancing communication; and promoting efficient use of resources. However, when entering into a partnership with a non-Federal body, there are ethics principles and legal considerations that should be weighed to ensure that we are acting in the best interest of the Government and public.

Certain rules, which derive from criminal statutes, Government-wide Standards of Ethical Conduct, and the Department's Supplemental Standards of Ethical Conduct, apply to the behavior of individual employees.

Other principles, which might be termed collectively as institutional ethics, relate to the actions of the agency *qua* agency; that is, to circumstances when the agency is acting in its institutional capacity. Although there is sometimes a temptation to superimpose on the agency the legal terminology, which derives from the rules applicable to individual employees, it is important to remember that such legal terms of art, which are applicable to individual employees, are not legally binding on the agency with respect to its institutional behavior. Instead, the principles discussed below under the category of institutional ethics should be viewed as prudential in nature—that is, the guidance describes standards that may be utilized prudentially to prevent public perception concerns, and to demonstrate that the agency has established self-limiting procedures designed to display that it is a trusted steward of its delegated authorities. They are not, however, legally binding on the agency when acting in its institutional capacity, and can be modified by agency management when deemed appropriate. The legal and ethical issues typically raised by leveraging arrangements and which should be addressed before implementing a leveraged project are:

- whether the arrangement is a gift or an augmentation of appropriations (Section B);
- whether the agency has improperly delegated its authority (Section C);
- whether there are any real or apparent conflicts of interest (Section D);
- whether the guiding principles regarding co-sponsorships have been followed (Section E);
- whether the activity should be initiated through notice and comment rulemaking (Section F);

- whether the agency is governed by the procedures of the Federal Advisory Committee Act (Section G);
and
- whether the arrangement presents problems regarding intellectual property rights (i.e., logos, stationery, broadcast rights, patents, or copyrights) (Section H).

This document provides a general discussion of these seven issues. It should help you identify whether a particular leveraging arrangement presents a legal issue that should be addressed, but it will not answer every question you may have regarding that issue.

Please contact your Leveraging Contact if you believe a potential leveraging arrangement raises any of these legal issues.

B. Does the Leveraging Arrangement Involve a Gift to the Agency or an Augmentation of Appropriations?

As a general rule, Federal agencies must operate within the limits of appropriated funds and may not supplement their appropriations with funds from other sources. However, if Congress has specifically granted gift acceptance authority to an agency, the agency may accept funds or "in kind" gifts from outside sources.

As a component of PHS, FDA has statutory gift acceptance authority under 42 U.S.C. § 238.

1. Gifts To Individual Employees

Under the Standards of Ethical Conduct, an employee may not accept a gift that is offered to the employee because of his Government affiliation, or which is offered by a "prohibited source." A prohibited source includes any person or organization who is regulated by the agency, does or seeks to do business with the agency, is seeking official action by the agency, can be substantially affected by the employee's official duties, or is an organization a majority of whose members fall into one of these categories. The regulations contain a number of exceptions which allow employees to accept certain classes of gifts which would otherwise be prohibited; major exceptions include one for gifts valued at less than \$20, and one for invitations to widely attended gatherings, such as an invitation to an awards dinner, an industry association reception or conference.

2. Gifts To The Agency

Under Federal law, the agency has certain authority to accept gifts in its institutional capacity; that is, gifts that are not intended to benefit individual employees but which are intended to aid or facilitate the programs or operations of the agency itself. As a regulatory agency, however, the agency's gift

acceptance authority should be exercised judiciously to avoid the appearance that the agency's programs or operations may be compromised.

In exercising its gift acceptance authority, the agency balances the importance of a potential gift against the potential appearance problems that may be caused by acceptance of the gift. Some steps to be considered in the balancing test:

- a. Determine the agency's interest in accepting the gift - what is the value of the gift to the agency.
- b. Determine if accepting the gift would reflect unfavorably on the ability of the agency or any employee to carry out its responsibilities or official duties in a fair and objective manner.
- c. Would acceptance of the gift compromise the integrity of, or the appearance of the integrity of, a governmental program or of any official involved in that program? Is there an apparent conflict of interest?
- d. Is the donor a prohibited or non-prohibited source? Since FDA is a regulatory agency, any gift from a prohibited source is subject to a higher degree of scrutiny.
- e. What is the nature and sensitivity of any matter pending before the agency that would affect the interests of the donor?
- f. What is the effect of accepting the gift on entities that are outside the agency? For example would any identifiable class of persons or entities be benefited or disadvantaged by the acceptance of the gift by the agency? If yes, to what extent?
- g. Would the size or the nature of the gift alone raise a significant appearance concern?
- h. Why is the gift being offered?
- i. What are specifically known or ascertainable reasons that may raise or diminish appearance concerns?
- j. Weigh the agency's interest in accepting the gift against any actual or apparent conflict of interest.
- k. When establishing the value of the gift to the agency consider the extent to which the gift is related to or will enable the agency to accomplish its mission; and the practical effect of the gift within the agency.

3. Loan of Equipment by a Private Party

Because FDA is authorized to accept gifts, it may also accept a loan of equipment by a private party without charge to be used in connection with particular agency work. The agency may pay for repairs to the equipment, but only to the extent necessary for the continued use of the equipment for Government work, and not after the Government's use has terminated.

4. FDA Requirements Concerning HHS-348 Travel (31 U.S.C. § 1353, acceptance of non-Federal support for travel)

- a. Acceptance of cash or in-kind services from non-government sources is the exception and not the rule.
- b. Employees must not solicit the payment of travel expenses from non-Federal sources.
- c. Acceptance of travel expenses must not create an actual or apparent conflict of interest.
- d. Employees are permitted to accept only those expenses which would otherwise be reimbursed by government travel regulations.
- e. An employee on official travel may not receive an honorarium or retain cash in excess of reimbursable expenses. If a check is provided to the traveler to cover expenses, it may not be cashed or kept; instead the check is to be endorsed to the Food and Drug Administration Receivable Branch, HFA-121, Room 11-88.
- f. Travelers may accept nothing more than nominal expenses (e.g., a ride from a meeting place back to a hotel) without advance approval and/or subsequent reporting. Employees are cautioned that even such "nominal expenses" should not give the appearance that the sponsoring organization is gaining some advantage in the employee's decision process.

C. Does the Proposed Leveraging Arrangement Involve Delegation of Agency Authority?

1. Generally, FDA may delegate authority to a private body if:

- a. There is no evidence that the private group serves any private interest that would prevent it from being impartial.
- b. The private group exercises its authority under the supervision of agency officials.

- c. The private group exercises authority under adequate standards.
- d. The arrangement does not confer power to make a final decision, unreviewable by the agency.
- e. The agency actually exercises its authority to make final decisions.

D. Does the Proposed Leveraging Arrangement Present Potential Institutional Conflicts of Interest or Other Ethical Concerns?

1. A federal employee may violate 18 U.S.C. § 208 by participating in an official matter that affects the financial interest of an outside organization in which the individual serves as officer, director, or trustee, even where the individual serves on official duty.

Such positions entail fiduciary duties to the outside organization in the conduct of the organization's affairs, and these fiduciary duties conflict with the principal duty of loyalty that every federal employee owes to the United States in the conduct of official activities.

- a. **Exceptions.** A federal employee may serve as officer, director, or trustee of an outside organization in an official capacity if:

- i.* there is special statutory authority;
- ii.* the organization has released the individual from all fiduciary obligations, consistent with state law; or
- iii.* the Government has granted the individual a waiver of the conflict of interest prohibition, under 18 U.S.C. § 208(b)(1).

2. An FDA employee may serve in an organization in a purely private capacity, as an outside activity. An employee who engages in an outside activity as officer, director, or trustee of an organization must recuse him- or herself from any FDA matter that affects the financial interest of the organization. See 18 U.S.C. § 208. Likewise, the employee would have to avoid any appearance of using his or her public office for the private gain of the outside organization. See 5 CFR § 2635.702. Moreover, the employee would have to comply with the usual rules governing outside activities. See 5 CFR Part 2635, Subpart H. This would include the requirement of prior administrative approval in many cases. See 5 CFR § 5501.106(d).

3. An Employee may be Assigned as a "Federal Liaison" to an Organization

As a federal liaison, the employee would be the FDA representative to the organization, and would present and receive information and views on behalf of the agency. The liaison's only duty is to the Government.

4. Practical Considerations

When acting institutionally, the agency should take into account the following prudential guidelines.

- a.** In structuring partnership arrangements, the agency should try to avoid the appearance of endorsing our partner's general policies, activities or products.
- b.** Avoid partnerships that create the appearance of preferential treatment toward the partner or the endorsement of the partner with respect to other matters pending before the agency.
- c.** Choose partners fairly. If the agency repeatedly partners with certain entities to the exclusion of other qualified potential partners, the agency will be open to criticism for showing favoritism. When practical, the agency should make the opportunity for co-sponsorship known to potential partners; this may be accomplished by publishing a Federal Register notice announcing the opportunity for a co-sponsorship.
- d.** Where possible, find partners that are not "prohibited sources" (e.g., regulated industry, contractors, and trade associations).
- e.** When there is a proposal to partner with an entity that would be considered a "prohibited source," demonstrate that the benefits to the Agency of partnering with a prohibited source clearly outweigh any potential appearance of undue influence or preferential treatment.
- f.** Adhere to all statutory and regulatory restrictions when entering into an outside leveraging partnership so that no issues of illegal augmentation of appropriations arise.
- g.** How relevant and timely is the topic to the agency's public health mission?
- h.** How unique is this particular opportunity?
- i.** What is the size of the audience reached (are multiplier opportunities considered)?

- j. What are the travel and other costs to the agency of participating in the collaboration?
- k. What impact will the employee's focus on the outside project and/or his/her absence have on the agency's workload?

5. Recusal/Disqualification

a. A General Overview

As discussed above, under 18 U.S.C. § 208, an employee is prohibited from participating personally and substantially in any particular matter that is likely to have a direct and predictable effect on the employee's own financial interest or on the financial interests of other persons or organizations whose interests are imputed to the employee under the statute. An employee must take steps to disqualify him- or herself from participation in such matters; disqualification (sometimes called "recusal") is accomplished by not participating in the particular matter.

b. Scope of the Recusal

The recusal must be complete; the employee may not pick and choose various aspects of a matter to work on. The recused employee needs to understand that a recusal does not just cover the making of a final decision on a matter; it covers participating in the matter by making proposals or recommendations, planning, advising, implementing the decision, as well as making any decision in the matter. It also precludes giving directions on a project to subordinates.

6. Standards of Ethical Conduct

Executive Order 12674, the Standards of Ethical Conduct for Employees of the Executive Branch, and the HHS Supplemental Standards of Ethical Conduct, also contain rules which govern the ethical issues applicable to individual Government employees. These ethical standards were written to assure that employees conduct Government business effectively, objectively, and without improper influence. Employees should read these rules and ensure that they are in compliance with requirements.

In addition to the disqualification/recusal requirement contained in 18 U.S.C. § 208 relating to financial conflicts of interest, there are also appearance issues that may need to be considered. A provision of the Standards of Ethical Conduct, 5 CFR § 2635.502, provides direction on how to analyze a situation that falls outside the scope of 18 U.S.C § 208 but which nevertheless may raise an appearance concern or may cause someone to question an employee's impartiality in the matter. Such a situation is likely to arise where an employee

has a "covered relationship" with someone who is a party, or is representing a party, to a particular matter involving specific parties, such as a new drug application, contract, or lawsuit. An employee is deemed to have a "covered relationship" with the following:

- a. a person with whom the employee has or seeks a business, contractual, or other financial relationship other than a routine consumer transaction;
- b. a person who is a member of the employee's household, or who is a relative with whom the employee has a close personal relationship;
- c. a person for whom the employee's spouse, parent, or dependent child is, to the employee's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee;
- d. any person for whom the employee has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee; or
- e. an organization, other than a political party, in which the employee is an active participant.

7. Evaluation of an Identified Appearance Problem

After the employee has brought a potential appearance problem to the attention of the agency through his or her supervisor, the agency must decide whether there is in fact an appearance problem that would prevent it from undertaking the leveraging project. In making that decision the agency must determine whether any reasonable person would question the propriety of the employee's participation in the matter, or whether the interests of the Government in the employee's participation outweighs the potential appearance problem. In making the latter determination, the agency may consider the following factors:

- a. the nature of the relationship involved;
- b. the effect that resolution of the matter would have on the financial interests of the person involved in the relationship;
- c. the nature and importance of the employee's role in the matter, including the extent to which the employee is called upon to exercise discretion in the matter;
- d. the sensitivity of the matter;
- e. the difficulty of reassigning the matter to another employee; and

- f. adjustments that may be made in the employee's duties that would reduce or eliminate the likelihood that a reasonable person would question the employee's impartiality.

E. Would the Proposed Leveraging Arrangement Involve Co-Sponsorship?

1. Definition:

Co-sponsorship refers to the joint development of a conference, seminar, symposium, educational program, public information campaign, or similar event related to the mission of the agency, by FDA and one or more non-Federal entities that share a mutual interest in the subject matter. For reasons discussed below (under "Legal Requirements"), this definition excludes prospective co-sponsors that would provide only funding for an event, as well as prospective co-sponsors that do not have a demonstrable substantive interest in the subject matter of the event.

2. Basic Principles of Co-Sponsorship are Contained in Appendix C.

3. Follow the Attached Model Co-Sponsorship Agreement in Appendix D.

F. Should the Proposed Leveraging Arrangement be Accomplished Through Notice and Comment Rulemaking?

Some agency actions or programs may be initiated only if the agency first engages in notice and comment rulemaking. As a general matter, notice and comment rulemaking is required if:

1. the effect of the program will be in some cases to confer and deny benefits that were not granted to regulated industry before the program was initiated;
2. the program binds others to meet certain requirements in order to participate in the program and thereby receive the benefit of the program; or
3. the program binds the agency with respect to how it treats others.

For example, in a recent Occupational Safety and Health Administration (OSHA) case, the court held that a directive issued by OSHA, under which each employer in selected industries would be inspected unless it adopted a comprehensive safety and health program designed to meet certain standards, was subject to notice and comment requirements.

G. Would Federal Advisory Committee Act (FACA) Procedures Apply to the Proposed Activity?

1. FACA prohibits federal agencies from establishing or using committees to provide advice or recommendations to the agency unless FACA procedures are followed.
2. Meetings exclusively between Federal officials and elected officers of State, local, and tribal governments are exempted.
3. Committees formed by the National Academy of Sciences (NAS) are exempted.
4. You are generally required to follow FACA procedures when consulting or collaborating with an outside person if:
 - a. as part of the proposed activity, a group with a cohesive, organized structure or purpose is created by, or at the direction of, directly or indirectly, a federal official;
 - b. the purpose of the proposed group is to give advice or recommendations on a particular matter or policy (e.g., draft regulations, guidance documents, recalls, scientific questions);
 - c. the advice or recommendations of the proposed group are to be given to the official or agency; and
 - d. the advice or recommendations forthcoming from the proposed group are those of the group, rather than those of each of the individuals in the group.
5. You are generally not required to follow FACA procedures if:
 - a. the group is formed to give advice or recommendations to non-governmental entities (e.g., to industry).
 - b. the group is brought together for administrative convenience so the agency can obtain advice or recommendations from the individual members of the group (but not the collective advice of the group).
6. Neither FACA nor the Freedom of Information Act (FOIA) requires that advisory committees disclose confidential, trade secret, or deliberative material, either orally in meetings, or in written memoranda, that otherwise would be exempt from disclosure in the hands of the agency.

7. Disclosure of agency records to an advisory committee does not constitute disclosure to the public, but triggers the requirement to review the records and release to the public any nonexempt records.

H. Will the Proposed Leveraging Activity Involve Intellectual Property Issues?

1. Use of Logos

- a. Determine whether the proposed logo infringes on an existing trademark. If it doesn't infringe on an existing trademark, consider registering the logo.
- b. It is best if FDA retains sole ownership of the logo so that there is no question as to who controls its use. It is also a good idea to discuss how the logo will be used.

2. Use of Stationery

- a. Government letterhead should be used for communications with joint signing only if the communication does not involve a matter for which the Government must maintain sole or primary responsibility (e.g., instructions to federal employees or for issuing federal grants or contracts).
- b. FDA should maintain control over what is said in any communication on Government stationery, as well as any communication that involves the Government on stationery referring to a collaborative arrangement.
- c. There should be a prior understanding as to the disposition of any remaining stationery at the end of FDA's participation in the collaborative effort.

3. Sale of Rights to Broadcast a Television Program Produced by FDA

- a. FDA should not apply the proceeds of the sale of broadcast rights to production of future programs.
- b. Videos of the program prepared by FDA employees can not be protected by copyright. This is because, under the copyright statute, material prepared by a government employee in the course of his or her employment is in the public domain as a work of the United States Government. 17 U.S.C. §§ 101, 105.
- c. If videos of the program are prepared by independent contractors, the contractors may be required to assign their copyright interest to the government as a term of the contract.

4. FDA's Property Interest in an Employee's Scientific Discovery

- a.** In general, any discovery by a government employee, made in the course of employment, is the property of the government.
- b.** If any one of the following would apply to the contemplated leveraging project, consult with your Leveraging Contact or Technology Development Coordinator/Liaison for advice on how to proceed:
 - i.** The discovery would be due in whole or part to taxpayer-financed FDA research.
 - ii.** Other related FDA research projects have been or are being conducted.
 - iii.** FDA encouraged and supported the employee's work that would lead to the potential/anticipated discovery.
 - iv.** Other FDA employees have been or would be involved in the research.
 - v.** FDA has had, or would have control over the research that would lead to the discovery.
 - vi.** FDA has exercised or would exercise this control (i.e., directed the nature of the research).
 - vii.** FDA equipment, supplies, or other resources have been, or would be used during the research.

For more detailed information go to:

<http://www.fda.gov/oc/ofacs/partnership/techtran/1stpg.htm>

Chapter 6 – Internal Review and Sign-off

Given the potential need to deal with various kinds of conflict and control issues, the growth and ultimate success of FDA leveraging will depend in part on management's knowledge of, and clear support of, new projects and risk-taking initiatives. This chapter describes a suggested plan for Agency management support of staff leveraging efforts. The plan entails providing supervisory oversight appropriate to, and not excessive for, the level of novelty or risk expected for a proposed leveraging project. The plan includes the formation of an Agency-wide Leveraging Consultant Council to address those special projects that would benefit from early review and support from Agency senior leaders. Below is an outline of the proposed "risk-based" review for new leveraging proposals and other leveraging issues. Appendix F presents the charter for the Leveraging Consultant Council.

A. "Risk-Based" Review of Proposed Leveraging Projects

Virtually all leveraging projects are likely to require some level of commitment of Agency resources (even if limited to some amount of staff time during the proposal stage). In addition, the proposed project may also involve some potential for legal or ethical conflict, policy, or appearance issues. In each of these cases, the proposing staff --who are working hard to make this leveraging happen-- will want Agency management to be aware of, and to be supportive of, the staff's activities and initiatives. The goal of the proposed review process is to provide that base of management knowledge and support without making it overbearing or "bureaucratic".

To meet this goal, the Agency has drafted a "risk-based" approach. The number of levels of review would depend on the degree of risk, as determined by the proposing staff's Center and Office, based on the legal, ethical, policy, or appearance issues for the project. Prior to Office level review, there will likely be preliminary reviews at the Branch or Division levels.

1. Proposed Levels of Review:

All Projects are reviewed at the Office Level (or Branch and/or Division level as determined by the Office); some will be reviewed at the Center level; and it is likely that only a few will be reviewed at the Agency level.

a. Office-Level Review of Every Leveraging Proposal

The first level of review is that done by the originating Branch, Division or Office. This is likely to be the only review required in most cases. The Office can determine whether the proposed project involves established mechanisms and familiar arrangements. Based on this review, the Office can give the go-ahead for most projects.

b. Center-Level Review of Some Leveraging Proposals

If the Office determines that the proposal would benefit from further review, then the next level of review would be done by the “local consultants” on leveraging within the Center. This may include higher program management, ethics and legal staff, financial experts, and the Leveraging Contacts. The Consultants can determine whether the issues flagged by the Staff Office are ones that have precedents within the Center or elsewhere in the Agency. If there is an Agency precedent, then it is assumed that an Agency policy has been articulated or inferred from the handling of the previous case(s). For leveraging proposals that merit a Center-level review, the Center can give the go-ahead to the project. However, if the Center-level consultants think that the proposal needs an Agency-level vetting, then the proposal would be referred to the Leveraging Consultant Council.

c. Agency Review of a Few Leveraging Proposals - Leveraging Consultant Council

It is expected that relatively few leveraging projects will merit Agency-level review and discussion by the Leveraging Consultant Council. These would be projects that may “break new ground” in terms of legal, ethical, policy, or appearance issues.

The Leveraging Consultant Council consists of high-level Agency leaders, whose role is to support leveraging, while maintaining the Agency’s high standards. As needed, additional staff/experts may attend Council meetings, e.g., other Center representatives, legal and ethics experts, and financial office advisors.

These significant leveraging proposals may require continued dialogue, good-faith negotiations and timely decisions relating to prospective collaborators. The Leveraging Consultant Council is committed to work with the Center and Office staff to search for ways to optimize leveraging that takes place within the Food and Drug Administration.

Appendix A - Suggested Leveraging Concept Worksheet

Leveraging Concept Worksheet (sample)

Date:

Staff/ Submitter Name:

Phone / email:

Title (for Project):

Overall goal of project:

Background/ Description of Public Health/Product Safety Problem:

Baseline measures describing size/status of Problem (if available):

FDA needs (actions, resources, capabilities) – to respond to Problem (Be specific):

Purpose of the project (Include list of key activities, if identifiable and required):

Results wanted (Be as specific as possible):

Agency/program resources & staff available – to involve in project:

Capabilities needed from collaborators (List all you think of; as specific as possible):

Potential Collaborators (List all you think of):

Your ideas for potential leveraging mechanisms:

Appendix B - Checklist for Outside Leveraging -- Ethical Concerns

Adherence to Guidelines:

- Is the Center able to manage any financial conflict of interest stemming from the partnership? Yes ___; No ____.
- Have you made efforts to avoid the appearance of conflicts or the endorsement of the partner? Yes ___; No ____.
- Have you made efforts to avoid preferential treatment of any private organization? Yes ___; No ____.
- Have you tried to choose partners fairly or were there any extenuating circumstances that made your choice reasonable and defensible? Yes ___; No ____.
- If partnering with a prohibited source, were efforts first made to find partners that were not prohibited sources? Yes ___; No ___; Not Applicable ____.
- Does your justification demonstrate that the benefits to the Agency clearly outweigh any potential appearance of undue influence or preferential treatment? Yes ___; No ____.

Other Questions: (Optional factors to be considered when entering into a partnership -- which deal with the integrity and the relevance of the project.)

- Is the topic of the partnership relevant and timely? Yes ___; No ____.
- Does the size of the audience justify the agency's investment in the partnership? Yes ___; No ___; Not Applicable ____.
- Will this partnership have a neutral or positive impact on the agency's resources (time and money)? Yes ___; No ____.

Note: If your answer is no to any item above, please check with your Center's Ethics Officer or the Agency's Ethics Staff before proceeding with the paperwork.

Appendix C - Basic Principles of Co-Sponsorship

1. It is particularly important to avoid the appearance that co-sponsorship of an event with an outside entity constitutes agency endorsement of the general policies, activities, or products of that entity.
2. There must be no appearance that the co-sponsor's support of an event will improperly influence FDA or any agency employee in other official matters in which that entity may have an interest. FDA must abide by all legal restrictions on the use of Federal funds and all applicable appropriations law requirements.

3. Legal Requirements for Co-Sponsorship

Subject to the restrictions below, FDA may enter into co-sponsorships with non-Federal entities.

- a. **Funds-Only Contributors.** FDA may not enter into a co-sponsorship with a non-Federal entity that would contribute funding, logistical services, or other material support for an event, but would not participate in the development of the substantive aspects of the event. Such a contribution might constitute an augmentation of appropriations and may not be accepted, unless authorized by an applicable agency gift acceptance statute or other statutory authority.
- b. **Substantive Interest of Co-Sponsor.** Non-federal entities that will be co-sponsors must have a demonstrable substantive interest in the subject matter of the event. Although entities without such an interest are not permissible co-sponsors, FDA may be able to accept from such entities a contribution of goods or services, under an applicable agency gift acceptance statute or other statutory authority.
- c. **Registration Fees.** Unless otherwise provided by statute, any registration fees collected by FDA must be deposited in the Treasury of the United States, without deduction for any charge or claim. 31 U.S.C. § 3302 (Miscellaneous Receipts Act). However, a non-Federal co-sponsor may collect fees to cover its share of the expenses of the event.
- d. **Free Attendance for FDA Employees.** If FDA and the non-Federal co-sponsor agree that FDA employees will be allowed to attend an event for free, then FDA employees may do so, at the discretion of their supervisors. However, in the absence of an agreement covering this issue, employees may accept individual offers of free attendance, on a case-by-case basis, only if such acceptance would not improperly augment the agency's appropriations or violate the Standards of Ethical Conduct for Employees of the Executive Branch. See, e.g., 5 CFR § 2635.204 (g) (widely attended gatherings). Ordinarily, the issue of

free attendance for FDA employees should be settled at the outset of the planning for the event.

For these purposes, free attendance includes the waiver of all or part of any registration fee, and the provision of food, refreshments, entertainment, instruction, and materials, furnished to all attendees as an integral part of the event. Free attendance does not include travel expenses, lodgings, entertainment collateral to the event, or meals taken other than in a group setting with all other attendees, although such benefits may be accepted in certain circumstances under other authorities.

- e. **Government Property.** FDA equipment, supplies, envelopes, or other property or personnel resources may not be made available for use by a non-Federal co-sponsor unless used to assist in the development or presentation of the co-sponsored event.
- f. **Independently Sponsored Portions of An Event.** Occasionally, a non-Federal co-sponsor may want to sponsor a discrete portion of an event independently. FDA staff may not assist a co-sponsor in planning or otherwise organizing any discrete portion of an event that is exclusively sponsored by the co-sponsor, except to the extent necessary to coordinate the overall program. Furthermore, FDA staff may not use or provide FDA equipment, supplies, or penalty envelopes to promote an independent portion of the event that is not sponsored by FDA. However, official announcements and brochures may contain factual references to the existence and scheduling of the entire event, including those portions of the event that are sponsored solely by a non-Federal co-sponsor, and FDA may participate in the preparation and distribution of such materials.
- g. **Fundraising by FDA.** FDA staff may not engage in fundraising, or solicitations for donations of any kind, to support an event, except as may be authorized by law. FDA staff may not solicit any gifts for the agency, for any purpose whatsoever, absent statutory authority. Furthermore, FDA should not assist in any fundraising efforts designed to meet a co-sponsor's share of the costs of an event; such efforts too easily may be perceived as and may in fact become attempts to raise funds to benefit the agency itself.
- h. **Internal Government Events.** FDA may not co-sponsor an event where attendance is limited to Federal employees. If a non-Federal entity contributes to an event that is attended solely by Federal employees, the arrangement should be viewed as a gift, not a co-sponsorship; such contributions may be accepted only pursuant to an applicable agency gift acceptance statute or other statutory authority.

- i. FDA Payment for Food and Refreshments for Employees at Their Official Duty Station.** FDA may not spend appropriated funds to pay for the costs of food and refreshments for FDA employees attending a co-sponsored event at their official duty station, unless:
- i.* the event is an authorized training program, pursuant to the Government Employees Training Act, 5 U.S.C. § 4101 et seq., and the provision of food and refreshments is considered necessary to achieve the objectives of the training program;
 - ii.* the event is a meeting, under 5 U.S.C. § 4110, that involves matters of interest to governmental and nongovernmental participants; the food and refreshments are incidental to the event; the partaking of the food and refreshments is necessary for FDA employees to participate fully in the event; and the FDA employees attending the event would miss essential formal discussions, lectures, or speeches concerning the purpose of the event if they took their meals or refreshments elsewhere;
 - iii.* the event is a meeting, under 5 U.S.C. § 4110, and FDA is charged a single registration fee covering both attendance and meals for employees; and there is no separate charge made for meals;
 - iv.* the payment is specifically authorized by other legislation; or
 - v.* The payment is for “light” refreshments as defined in 41 CFR § 301-74.11.
- j. FDA Payment for Food and Refreshments for Non-Federal Attendees.** FDA may not spend appropriated funds to pay for the costs of food or refreshments for non-Federal attendees at a co-sponsored event, unless:
- i.* the event is an authorized training program, pursuant to the Government Employees Training Act, 5 U.S.C. § 4101 et seq., and the non-Federal attendee is officially participating as a speaker at the event;
 - ii.* the payment is authorized by 5 U.S.C. § 5703, because the non-Federal attendee has been invited by FDA to serve without pay as a speaker or official participant at the event (mere attendance at the event without direct service to FDA is not sufficient), and the non-Federal attendee is away from home or regular place of business;
 - iii.* the payment is authorized, by an applicable appropriations act, to be made from a Reception and Representation Fund;
 - iv.* the payment is authorized, by section 505 of Public Law 102-394 (see note to 31 U.S.C. § 1345), to be made from HHS appropriations, in order to defray the expenses of attendance by non-Federal personnel at meetings that are

concerned with the functions or activities for which the appropriation is made or that will contribute to improved conduct, supervision, or management of those functions or activities; or

v. the payment is specifically authorized by other legislation.

k. FDA Payment for Travel of Non-Federal Attendees. FDA may not spend appropriated funds to pay for travel expenses of non-Federal attendees at a co-sponsored event, unless:

i. the payment is authorized by 5 U.S.C. § 5703, because the non-Federal attendee has been invited by FDA to serve without pay as a speaker or official participant at the event (mere attendance at the event without direct service to FDA is not sufficient), and the non-Federal attendee is away from home or regular place of business;

ii. the payment is authorized by Section 505 of Public Law 102-394 (See note to 31 U.S.C. § 1345) to be made from HHS appropriations, in order to defray the expenses of attendance by non-Federal personnel at meetings that are concerned with the functions or activities for which the appropriation is made or that will contribute to improved conduct, supervision, or management of those functions or activities; or

iii. the payment is specifically authorized by other legislation.

l. Social Events. FDA may not co-sponsor an event that would be primarily social in nature. FDA may co-sponsor an event that has a social component (such as a modest reception), as long as the event has a primarily educational or informational purpose that is related to a mission of the agency.

m. Co-sponsored Conferences Involving Employee Travel. A senior agency official must authorize any FDA co-sponsorship of a conference that involves travel by 30 or more FDA employees. 41 CFR § 301-16.3. In general, FDA must minimize travel costs by authorizing the minimum number of attendees necessary to accomplish the agency's goals. 41 CFR § 301-16.1.

n. Fiscal Responsibility and Conference Planning. FDA shall exercise strict fiscal responsibility by, among other things, selecting conference sites that minimize administrative costs, travel costs, and time costs. 41 CFR § 301-16.1. For further details about fiscal responsibility requirements, consult 41 CFR § 301-16 ("Conference Planning").

4. Additional Guidance on Co-Sponsorship

- a. **Co-Sponsor Created for Event.** As a general rule, FDA should not co-sponsor an event with an entity created solely for involvement in that particular event. In exceptional cases, however, special circumstances or agency needs may reasonably require a co-sponsorship with an entity that is newly created for the purpose of developing the event. In such cases, FDA must exercise special caution to ensure that the new entity is not merely a vehicle for other persons or organizations that would be inappropriate co-sponsors themselves.
- b. **Agreements and Records.** Unless there are exceptional circumstances, FDA and its co-sponsors should complete a written co-sponsorship agreement and should do so well in advance of an event.

(Please refer to the **Model Co-Sponsorship Agreement** in Appendix D).

Agreements and records concerning co-sponsored events should account fully and accurately for each party's programmatic and financial responsibilities and activities. Agreements and records should describe separately any discrete portion of an event that will be exclusively sponsored by FDA or exclusively sponsored by a non-Federal entity. Agreements and records concerning the amounts, sources, and uses of funds should be made available to the public upon request. FDA may not co-sponsor an event with an entity that will not make information concerning funding publicly available.

- c. **Prohibited Sources.** Any proposed co-sponsorship with an entity that would be deemed a "prohibited source," under the Standards of Ethical Conduct for Employees of the Executive Branch, should be reviewed with particular care. A "prohibited source" is any person or entity that:
 - i.* is seeking official action by the agency planning the event;
 - ii.* does business or seeks to do business with that agency;
 - iii.* conducts activities regulated by that agency;
 - iv.* has interests that may be substantially affected by the performance or nonperformance of the official duties of an employee of that agency; or
 - v.* is an organization the majority of whose members are described in *i* through *iv* above.
- d. **Factors to evaluate before entering a co-sponsorship agreement.** FDA must weigh the appearance of a conflict of interest against the importance of working with a given prohibited source as a co-sponsor. FDA should consider any facts that have a bearing on either the severity of the apparent conflict or the degree of

benefit to the agency from working with a particular prohibited source, including the following factors:

- i.* Is the event one which serves an important mission of the agency?
 - ii.* Is there another available co-sponsor that is not a prohibited source, or does the prohibited source have a special expertise or status that would make it the preferred co-sponsor of the event?
 - iii.* What would be the nature of the prohibited source's involvement in the event? To what extent will the prohibited source take an active and important role in the development of the substantive portions of the event?
 - iv.* Would co-sponsoring an event with the prohibited source create the appearance of partiality toward that source or the appearance of an endorsement of that source with respect to other matters that it has pending before the Government?
 - v.* Does the prohibited source regularly apply for contracts, grants, or other financial relationships with FDA? Do grants, contracts, or other financial relationships with FDA represent a significant percentage of the source's overall budget? If either of these is the case, FDA may not co-sponsor an event with that prohibited source unless the benefits to the agency clearly outweigh any potential appearance of undue influence or preferential treatment.
 - vi.* Are significant activities of the prohibited source regulated by FDA? If so, the agency may not co-sponsor an event with that prohibited source unless the benefits to the agency clearly outweigh any potential appearance of undue influence or preferential treatment.
- e. Fundraising By Non-Federal Co-Sponsors.** Often, a non-Federal co-sponsor will want to raise funds from various donors in order to help meet its allotted shares of the costs of an event. As a practical matter, FDA cannot become involved in scrutinizing the fundraising activities of its co-sponsors. However, a non-Federal co-sponsor must give the following assurances:
- i.* that any solicitation will make clear that the non-Federal co-sponsor, not FDA, is asking for the funds;
 - ii.* that the non-Federal co-sponsor will not imply that FDA endorses any fundraising activities in connection with the event; and
 - iii.* that the non-Federal co-sponsor will make clear to donors that any gift will go solely toward the expenses of the non-Federal co-sponsor, not FDA.

- f. **Commercialized Events.** FDA may not co-sponsor an event that is developed by the co-sponsor as a profit-making endeavor. Any registration fees charged to attendees should not be designed to exceed the co-sponsor's costs for the event. Educational materials related to the event may be sold to attendees at cost. Also, transcripts and recordings of a co-sponsored event may be sold at cost.
- g. **Promotion or Sale of Products.** FDA may not co-sponsor an event that is primarily devoted to promoting or selling a co-sponsor's products or services.
- h. **Event Publicity vs. General Endorsement.** Once a co-sponsored event has been approved, the co-sponsor may use its name in connection with FDA only in factual publicity for that specific event. Factual publicity includes dates, times, locations, purposes, agendas, fees, and speakers involved with the event. Such factual publicity should not imply that the involvement of FDA in the event serves as an endorsement of the general policies, activities, or products of the co-sponsor; where confusion could result, publicity should be accompanied by a disclaimer to that effect. (Note, however, that HHS may have authority, in certain circumstances, to give an endorsement to an organization whose activities further the mission of the Department. E.g., 5 CFR § 2635.702 (c) (1 & 2)). Non-Federal co-sponsors must agree to clear all promotional materials for the event with FDA to ensure compliance with these restrictions.
- i. **Seeking Qualified Co-Sponsors.** FDA actively may seek out qualified co-sponsors for a contemplated event. There are, however, two areas of concern with respect to the recruitment of potential co-sponsors:
 - i. **Appearance of Coercion.** FDA must be careful to avoid any appearance that it is coercing an outside entity to become a co-sponsor. This appearance is most likely to arise when the agency solicits potential co-sponsors who have interests that could be affected significantly by pending agency action. Therefore, great care should be taken when FDA actively solicits "prohibited sources" (see above) to become co-sponsors. Where practical, for example, FDA personnel who participate substantially in official matters affecting a non-Federal entity should not be the ones to make overtures toward that entity about a possible co-sponsorship.
 - ii. **Appearance of Favoritism.** FDA must be careful to avoid the appearance that it is showing favoritism by approaching only certain entities, when other qualified entities could derive a benefit from entering into the particular co-sponsorship with FDA. Where practicable, FDA should make the opportunity for a co-sponsorship known to all similarly situated entities. In some instances, for example, FDA might publish a Federal Register notice to announce the opportunity for a co-sponsorship. For some events, it may not be feasible to engage more than one co-sponsor or even to make the opportunity for a co-sponsorship known to all qualified entities; at the very

least, however, FDA should be able to articulate a reasonable basis for limiting its field of prospective co-sponsors.

Appendix D - Model Co-Sponsorship Agreement

FDA [or name of subcomponent] and [name of co-sponsor] agree to co-sponsor [name of event], according to the terms expressed below:

1. Background

[Provide the following information: (a) the nature and purpose of the event; (b) the identity and background of the co-sponsor(s); (c) the importance of the event to both FDA and the co-sponsor; (d) the substantive interest and special expertise of the co-sponsor in the subject matter of the event; (e) any other relevant background information that may explain the mutual interest of FDA and the co-sponsor in working together on the event.]

2. Responsibilities for Developing the Event

[Provide the following information: (a) the respective responsibilities of FDA and the co-sponsor for developing the substantive aspects of the event, such as the agenda and speakers; (b) the respective responsibilities of FDA and the co-sponsor for logistics and finances, such as arranging the paying for conference facilities, advertising, food, and any other event expenses. **Note: this is the core paragraph of the co-sponsorship agreement, and it should reflect as much detail as FDA and the co-sponsor reasonably can provide.**]

3. Registration Fees and Other Charges

[Provide the following information: (a) state whether the co-sponsor intends to charge registration fees, and, if so, state that the co-sponsor agrees to set a fee no higher than necessary to recover its share of the costs of the event; (b) state whether FDA and the co-sponsor agree that FDA employees will be allowed free attendance at the event; (c) state whether the co-sponsor intends to sell educational materials pertaining to the event or transcripts or recordings of the event, and, if so, state that the co-sponsor agrees to sell such items at cost.]

4. Independently Sponsored Portions of Event

[Provide the following information: (a) state whether either FDA or the co-sponsor intends to sponsor any discrete portion of the event independently; (b) describe any separately sponsored portion; (c) state that FDA resources, including staff, will not be used to develop, promote or otherwise support a portion of the event that is independently sponsored by the co-sponsor, although official announcements and brochures may contain factual references to the schedule of the entire event, including portions sponsored solely by the co-sponsor.]

5. Fundraising

[Name of co-sponsor] will make clear, in any solicitation for funds to cover its share of the event costs, that it, not FDA, is asking for the funds. [Name of co-sponsor] will not imply that FDA endorses any fundraising activities in connection with the event. [Name of co-sponsor] will not imply that FDA endorses any fundraising activities in connection with the event. [Name of co-sponsor] will make clear to donors that any gift will go solely toward defraying the expenses of [name of co-sponsor], not FDA.

6. Promotional Activity

[Name of co-sponsor] will not use the event primarily as a vehicle to sell or promote products or services. [Name of co-sponsor] will ensure that any incidental promotional activity does not imply that FDA endorses any products or services. [Name of co-sponsor] will make reasonable efforts, subject to FDA review, to segregate any incidental promotional activity from the main activities of the event.

7. Event Publicity and Endorsements

[Name of co-sponsor] will not use the name of FDA or any of its components, except in factual publicity for the specific event. Factual publicity includes dates, times, locations, purposes, agendas, fees, and speakers involved with the event. Such factual publicity shall not imply that the involvement of FDA in the event serves as an endorsement of the general policies, activities, or products of [name of co-sponsor]; where confusion could result, publicity should be accompanied by a disclaimer to the effect that no endorsement is intended. [Name of co-sponsor] will clear all publicity materials for the event with FDA to ensure compliance with this paragraph.

8. Records

Records concerning the event shall account fully and accurately for the financial commitments and expenditures of FDA and [name of co-sponsor]. Such records shall reflect, at a minimum, the amounts, sources, and uses of all funds.

9. Public Availability

This co-sponsorship agreement, as well as the financial records described in paragraph 8, shall be publicly available.

10. Co-Sponsorship Guidance

FDA and [name of co-sponsor] will abide by the legal memorandum of August 8, 2002, "Co-Sponsorship Guidance," issued by the HHS Designated Agency Ethics Official.

Appendix E - Relevant Statutes

1. Federal Conflict Of Interest Statutes

There are criminal conflict of interest statutes with which employees should be familiar. There are five Federal conflict of interest statutes of particular importance: 18 U.S.C. §§ 203, 205, 207, 208, and 209. Others that are also relevant are 18 U.S.C. §1905 and 21 U.S.C. § 331(j).

a. Representational Activities

18 U.S.C. §§ 203 and 205. These statutes generally limit representational activity, paid or unpaid, by Federal employees before Federal agencies or courts. They bar an employee from representing another party before a Federal agency or court on any particular matter in which the United States is a party or has a direct and substantial interest.

18 U.S.C. § 207. This statute prohibits a former Federal employee from representing another person or entity back to the U.S. Government, with the intent to influence, on a particular matter involving specific parties, in which the employee was engaged as part of his or her official duties while with the Government, or which a subordinate of the employee worked on during the employee's final year of Government service. Senior level employees also have certain additional restrictions limiting their representational activities after Government service.

b. Financial Interests

18 U.S.C. § 208. This statute bars an employee from participating personally and substantially as a Government employee in any particular matter in which the employee has a financial interest. These restrictions also apply regarding the interests of an employee's spouse; minor child; general partner; any organization in which the employee is serving as officer, director, trustee, general partner or employee; and any person or organization with whom the employee is negotiating for or has any arrangement concerning prospective employment. The Office of Government Ethics has issued regulatory exemptions under 18 U.S.C. § 208(b)(2), which can be found under 5 CFR Part 2640. Notwithstanding the regulatory exemptions, however, FDA employees who file financial disclosure reports are prohibited from holding financial interests in any significantly regulated entity.

c. Outside Compensation

18 U.S.C. § 209. This statute prohibits a Federal employee from receiving compensation from a source other than the United States Government for the performance of his or her official duties.

2. Federal Disclosure Statutes

- a. 18 U.S.C. § 1905.** This statute prohibits a Federal employee from disclosing trade secrets and similar information, which the employee obtains in the course of performing official duties or as a result of Government employment, unless authorized by law to do so.
- b. 21 U.S.C. § 331(j).** This statute prohibits a Federal employee from using to his/her own advantage or revealing (unless authorized) any information acquired under certain sections of the Food, Drug and Cosmetic Act concerning any method or process which, as a trade secret, is entitled to protection.

Appendix F - Charter for Leveraging Consultant Council

Purpose:

- To provide senior-level Agency support for the success of leveraging.
- To facilitate consistency in Agency approach and policy toward leveraging.
- To provide a forum for airing and resolving sensitive or precedent-setting leveraging issues.

Composition:

- Council Members currently include the Deputy Associate Commissioner for Regulatory Affairs and the Acting Associate Commissioner for Planning as Co-Chairs, the Chief Counsel, the Director of ORA's Performance Results Staff, the Acting Senior Advisor for Science, the Special Assistant to the Senior Associate Commissioner, the Director of Outreach in the Office of Commissioner, the Director of Executive Operations in CDER, the Director of CVM, and the Deputy Director of CFSAN. Council membership may change over time and will continue to include senior Agency managers of comparable responsibility.
- Council meeting participants may include expert advisors from other Offices, as appropriate to the proposals or issues discussed.

Process:

- Center Director determines that proposal or issue would benefit from Agency-level discussion. A manager or Leveraging Contact, after consultation with their Center Director, raises the issue with the Leveraging Consultant Council by:
 - 1) Sending an email to the Council Chairs and Executive Secretary for the Council with copies to the Council and Center-level involved staff, requesting that the proposal or issue be added to the agenda for the next Council meeting.
 - 2) Providing summary or brief background package to Council members in hard copy form and electronically, at least one week before the meeting.
- Members of the Leveraging Consultant Council can also raise issues for consideration by the Council.

- The Council will schedule meetings quarterly and will notify Center Directors, Deputy Directors and Leveraging Contacts of date, time, and location of the meetings.

Output:

- Advice on additional consultations or necessary modifications to proposed or current leveraging initiatives.
- Recommendations to Leadership Council on how to resolve issues that require the Leadership Council's input.
- Shared "Lessons Learned" on proposals and projects.