



Guidance for Collaboration with the Private Sector

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I. SUMMARY

The Centers for Disease Control and Prevention (CDC)⁽¹⁾ has developed guidance for employees to help evaluate the suitability of potential collaborations with the private sector. This guidance is based on several principles: public health decisions must be based on sound science and public good; benefits to society must be a higher goal than benefits to either partner in the collaboration; the agency must be a diligent steward of public trust and funds; and the agency and its employees should conduct business according to the ethical standards that govern the agency. Criteria used to determine whether to collaborate include: fit of collaboration to mission, independence of scientific judgment, effect of the potential collaborator's product(s) or service(s) on health, and the potential collaborator's behavior. General recommendations for collaboration address: consistency of potential collaborator's broad mission with agency's mission, use of indirect relationships, public nature of collaboration, and openness.

II. INTRODUCTION

Broad societal goals for health promotion and disease prevention cannot be achieved without widespread change in individual behavioral practices; optimal utilization of preventive services; improvement in diagnostic, treatment, and prevention technologies; and increased knowledge about and understanding of public health problems. The

assistance of both public and private organizations is required if societal change is to be achieved. The Centers for Disease Control and Prevention alone rarely has the resources needed to achieve large-scale implementation. Thus, the agency periodically considers partnerships, including ones with private sector organizations, to carry out its mission.

For purposes of this Guidance, a **collaboration is defined as an interaction between CDC and one or more private sector organization in which both parties work together to carry out their missions. The interaction is voluntary and the basis for the interaction is not found in statutory authority or other law.** Situations in which CDC is mandated to work with the private sector are not subject to the criteria and recommendations in this Guidance. For example, interactions with the private sector that CDC carries out as part of its Congressional authority such as responses to emergencies (e.g., epidemics, toxic spills, etc.) and health hazard evaluations or interactions covered by other laws or regulations (such as grants, cooperative agreements, contracts, and CRADAs) are not considered to be collaborations subject to the criteria and recommendations in this Guidance. Situations in which CDC is mandated to work with the private sector are also excluded. However, the principles in this guidance apply to all CDC activities.

The types of collaborations possible are many. For professional organizations, public grantees, and individual practitioners, the ethics and appropriateness of collaborations with private organizations have been greatly debated.¹⁻⁵ These debates generally concern issues of conflict of interest and duty to patients, workers, and the public. The responsibilities associated with using public funds and being public employees also affect what might otherwise be reasonable interactions.⁵

A dearth of literature is available on the ethics of, or the practical approaches to, such collaborations from which CDC can develop policy. The approach described here began with a series of discussions within CDC's National Center for Chronic Disease Prevention and Health Promotion and with outside experts on how best to assess and encourage partnerships with private organizations⁶ and how to assess the suitability of public/private collaborations. This approach was originally developed to guide industry collaborations within one CDC Center, but now has been broadened and modified for agency-wide use. (For further information, see Section VII, References.)

This document identifies principles that underlie the public health mission and sets forth guidance for evaluating potential collaborations. This document concentrates only on collaborations with private organizations, both for-profit and not-for-profit. Even with this guidance, the decision of whether to collaborate may still be unclear in some circumstances; no set of precepts can adequately cover all situations. Only if such collaborations were arbitrarily prohibited could judgment and oversight on a case-by-case basis be suspended.

III. COLLABORATION WITH THE PRIVATE SECTOR

Private sector organizations are not-for-profit or for-profit. Not-for-profit organizations include voluntary associations, foundations, civic groups, professional associations, universities, unions, and other similar types of groups. For-profit organizations include corporations, partnerships, proprietorships, and others intended to generate financial gain for their owners. The agendas and missions of private organizations may overlap to a greater or lesser degree with those of CDC. Even where such overlap exists, it is likely there are fundamental differences between CDC and private organizations.

Collaborations with the private sector may involve, but are not limited to:

- Technology transfer. Examples of technology transfer activities include the development and evaluation of commercial products such as vaccines, diagnostic tests, computer software, and media tools.
- Public education. Examples of public education activities include mass media campaigns, production and dissemination of educational materials, and direct client or patient intervention programs.
- Professional education. Examples of professional education include conference sponsorship and publication of proceedings, recommendations, or other materials.
- Applied research or evaluation. Examples of research and evaluation include development or assessment of the effectiveness of various commercial or pharmaceutical products and efficacy of nonpharmacologic interventions, investigations of etiology, evaluation of health protection and promotion activities, engineering control measures, and dissemination of results.
- Provision of public health services.

For purposes of this Guidance, collaborations are not considered to include interactions with the private sector that would occur as part of CDC's routine conduct of business such as responses to emergencies, health hazard evaluations, surveillance, and technical assistance. However, the principles undergirding this guidance should generally apply to all CDC activities.

Reasons for considering collaboration include access to private sector skills and enhancement of the program by involving outside partners. Exemplary organizations in an industry can set an example for other organizations. Organizations often possess information or technology that is useful to the public. Organizations provide access to at-risk worker populations. Engaging the private sector may be helpful in reaching a large segment of the public, generating broad societal support or winning over potential opposition. However, limited public resources or the expectation of gaining private resources alone should not be considered sufficient reason for collaborating with private organizations.

What the health agency and the private sector partners bring to the collaboration are often similar. Both may have resources to commit, and each may have access to specific populations or professional groups that the other cannot easily reach. In the best collaborations both groups bring credibility with selected segments of the population on certain issues and/or special technical expertise.

IV. PRINCIPLES OF PUBLIC HEALTH AND CDC

The mission of CDC is to prevent premature death, disease, injury and disability; to protect against hazardous environmental and occupational exposures; and to promote health. Other organizations may share much or part of this mission, but rarely is it central to a private organization's mission. Because much of the concern about collaborations arises from CDC's potential conflict of interest between its societal responsibility and responsibilities growing out of the collaborations, the agency must have its mandated mission clearly in mind when considering a collaboration. The following principles are presented to help insure that CDC is attending to its primary mission and to govern the assessment of the potential collaboration.

A. Public health decisions must be based on sound science and the public good.

B. The benefits to society must be a higher goal than benefits to either partner in the collaboration.

C. The agency must be a diligent steward of public trust and funds.

D. The agency and its employees should conduct business according to the ethical standards that govern the agency.

A number of issues should be addressed in deciding whether to enter into a potential collaboration. The relative contribution of each issue to the decision will depend upon the specific circumstances of the potential collaboration. The decision of whether to collaborate with a given private partner should be based on the preponderance of evidence gathered by addressing the issues.

The agency should execute, in advance, a concise, written agreement with the collaborating partner(s). The agreement should identify key elements of the project including: goals and intended benefits; the role and responsibilities of each partner; the resources each commits to the project; the rights to any property, goods, services, or other products of the project; the individuals acting as lead for each partner; and any reporting plans or requirements. The agency should review the agreement periodically as the project is implemented and update it as needed.

V. CRITERIA FOR ASSESSING POTENTIAL COLLABORATIONS

A. CDC should be clear how the potential collaboration fits within its overall mission and priorities and the private partner's mission and priorities.

If CDC originated the project, then it is likely to fit well with the agency's mission and goals. If the project was the partner's idea, the agency should assess whether the project is central to the agency's goals and priorities. The agency should consider the following questions:

- Why does the organization want to work with the agency?
- How does the project relate to the organization's mission and goals?
- Will the potential collaboration have a reasonably large impact relative to the resources required?

B. CDC should address independence and objectivity of scientific judgment in the potential collaboration. Further, mechanisms should be identified that will ensure such objectivity and independence during the collaboration.

The agency should consider the following questions:

- Will the project be designed so that it is scientifically defensible?
- Will CDC be able to review and approve any public statements about the project, its findings, and its implications?
- Will the agency have a say in data analysis, publication, and dissemination of results and materials?
- Will the agency or the private sector partner have unilateral veto power over what can be disseminated?
- Can either party halt the project because they become uncomfortable with the results or interpretations?

Answers to these questions should be agreed on in advance and put in writing.

Independence and objectivity are particularly critical when examining an issue surrounded by controversy. The fact and appearance of independent judgment can be protected in many ways, including establishing independent review boards of public health professionals and scientists who are not part of the project.

C. CDC should assess the effect of the private partner's products or services on health and whether they are compatible with CDC's mission.

The agency should consider the following questions:

- What is the overall impact of the organization's products or services, their distribution, mode of delivery, and their use on health?
- Do the organization's products or services harm the public's health when used as intended?
- What is the impact of the potential collaboration on the public's health?

Some organizations produce products that have aspects both harmful and beneficial to the public's health. When deciding to collaborate with these entities, the potential harm the product or service causes should be compared to the potential benefit of the product or service; the benefit to the public of the product or service should outweigh harm and be easily articulated.

By working with CDC, organizations producing harmful products or delivering harmful services can gain a measure of respectability. At the same time, CDC can open itself up to criticism by others in the health community and a potential loss of credibility. The collaboration should address the product's or service's harmful effects and it should clearly state how the collaboration fits within CDC's overall mission and priorities.

In negotiating the collaboration, the potential partner can be asked to provide a list of products or services. Common knowledge should suffice to determine the extent to which a product or service has a harmful component. If there is doubt about a product's safety, a more thorough review should be conducted.

D. CDC should assess the behavior of the private partner in conducting business and determine whether the partner's behavior is consistent with CDC's mission and the principles guiding private sector collaboration.

Questions regarding a variety of aspects about the organization's behavior should be asked.

- What is the history of the organization's previous collaborations with CDC or another public health agency?
- Do the organization and CDC adhere to similar scientific, ethical, and legal principles and practices?
- Will the organization comply with CDC's policy and regulations?
- What are the organization's practices in promoting its products or services and its interests?
- Could CDC stand behind the organization's practices?

- Does the organization's motivation for pursuing the collaboration fit with CDC's mission and priorities?
- How has the organization behaved in the past when its product or service was found to be harmful?

Generally, it is considered good business practice for commonly owned organizations to support each other's interests. In the specific case where an organization is owned by another (e.g., subsidiaries owned by a parent company) and either the parent company or one of the subsidiaries produces a product or delivers a service that is harmful, the issue of whether the organization supports the interests of the parent company or other commonly owned organizations should be addressed. The independence of the potential partner and whether the interests of the other commonly owned organizations will be supported by the collaboration should be addressed. Questions to ask include:

- Is there evidence that the potential partner has conducted activities that support the interests of other organizations?
- How independently is the organization able to conduct its business from the parent organization and affiliated organizations?

Most of these questions about partner's behavior in conducting business can be asked directly of the partner or assessed during the negotiation phase of the collaboration. In addition, a media search could be made to determine whether there have been press reports about the partner's behavior.

VI. GENERAL RECOMMENDATIONS FOR COLLABORATIONS

A. CDC should assess not only the specific area of mutual interest but the public impact of the partner's broad public mission and image. For highly controversial issues, multiple collaborators should be sought that represent a broad spectrum of opinions and interests.

In any collaboration, partners should share a common goal. But CDC should also be aware of the unshared aspects of the partner's activities. Areas of similarity of mission and interest are often well described in planning meetings, since these similarities are the basis for potential collaborations. However, the overall perception of the partner will inevitably color the public's view of the appropriateness of the collaboration. Will the collaboration enhance or detract from the agency's mission, image, and credibility?

Many potential partners hold public positions on controversial issues. Working on issues with such collaborators may compromise the agency. Findings or activities favorable to the collaborator's position could be met with public skepticism. One way to avoid this

skepticism and the agency being too closely tied to an individual organization's position is to collaborate with multiple partners.

B. CDC should avoid participating in indirect collaborations unless it would participate in a direct relationship with the partners.

A direct relationship is one in which the agency and private partners execute a project agreement. The most direct relationship is with a single organization. An indirect relationship occurs when the agency collaborates with an organization through an intermediary partner with whom the agency executes an agreement. Indirect relationships vary; for example, the agency may serve as a member of an advisory group for a project or may be a member of a large group conducting a project through a third party, such as a professional association.

Indirect relationships should not be established solely to distance CDC from a specific partner, thereby avoiding an external perception of an inappropriate collaboration. An indirect relationship often provides relatively little protection from the perception that the agency is inappropriately working with a private organization. This is especially true when a third party is the intermediary between the agency and a single organization.

C. Private partners should be informed that the existence of the collaborative relationship will be made a matter of public record. How this will occur should be worked out early, especially if implied endorsements are likely. No direct endorsement of a product or service is permitted by the agency.

Both CDC and the partner should be willing to make public the existence of a collaboration. For CDC the standard should be whether the agency could defend a collaboration about which the details were published on the front page of the local newspaper. Although publication of minutes from meetings is rarely required, private organization should be aware that all meetings are subject to public disclosure.

CDC should ensure that any stand taken on issues of public health importance is supported by the interests of the partner, the public, and the agency. This responsibility must be borne out in fact and in appearance because of the importance of the public's trust in the agency. The appearance of compromised principles may limit CDC's ability to carry out its public health mission as much as actual compromise.

Except where specified by law (e.g. the National Technology Transfer and Advancement Act) for public employees, no appearance or fact of personal gain should result from the collaboration. This responsibility becomes critical when collaborations are with a single organization or concern controversial subjects. Appearing to "do wrong" while "doing right" is really "doing wrong." Officials who appear to be doing wrong erode confidence in government and give citizens reasons to believe the government can not be trusted. Citizens often have no other way to judge actions other than by appearance. Public disclosure of the relationships can help reduce concerns about potential conflicts of interest.

CDC should assess how its name and participation in a collaborative project will be used and whether such usage is consistent with the agency's public role. A private partner may be eager to link its name with CDC. Both partners should understand how the collaboration might be publicized, and the agency should have the chance to review and approve how its name and participation will be used.

CDC should assess whether the partner will attempt to use its name to endorse a product. Implied endorsement could occur, for example, if the agency tested a specific product in a research project and did not include all possible products in the test. Collaborating with one organization (among several that provide the same product or service) may, in addition to possibly implying endorsement of that organization or its product, give a real or perceived (by its competitors) competitive advantage to the collaborator. No direct endorsement of a product or service is permitted by the agency.

At times, CDC is mandated to evaluate a product to determine whether it performs as intended. While it can certify performance, CDC does not endorse one product over another. For example, the National Institute for Occupational Safety and Health certifies selected worker protection equipment as meeting specified performance criteria.

D. CDC should maintain a process of openness and fairness in developing collaborations with partners on similar projects or projects with similar intent.

Openness to participation means CDC is willing to consider all potential partners for similar projects or projects with similar intent. Any organization can approach CDC regarding a potential collaboration. At the same time, CDC is sensitive to the need to protect private sector interests.

Under certain circumstances, particularly those involving proprietary information, knowledge, or technology, CDC can appropriately enter into exclusive partnerships with private organizations. Examples include Cooperative Research and Development Agreements (CRADAs), contracts, cooperative agreements, and grants. Establishment of these exclusive partnerships is generally preceded by a public announcement indicating openness to considering applications from any organization capable of providing the products or services necessary for a successful collaboration.

Under other circumstances, a collaboration may be most appropriate and successful when it includes many partners, especially when the idea was originated by the agency. One of the best ways to avoid potential criticism of exclusive partnerships is to offer to collaborate with all appropriate partners and collaborate with all of those who express interest. Under such an arrangement concerns about exclusivity are usually avoided since any organization could have participated.

E. Within each Center, Institute, and Office (CIO), a formal review and advisory process should be established for examining potential collaborations according to the principles, criteria, and recommendations described in this document.

The criteria for assessing potential collaborations and the recommendations outlined here are open to interpretation, and the characteristics of individual projects can affect the relative weight and interpretation of specific criteria and recommendations. Because any one unit within a CIO is unlikely to accumulate extensive experience with assessing potential collaborations, a review process should be established and provide advice on potential collaborations to the CIO Director. The implementation of the review process should be determined by each CIO; for example, it may be established as a separate process from the CRADA review or it may include the process to review CRADAs.

Individuals not directly involved in a potential collaboration should formally review the proposal at some stage in the negotiation process. This review serves several purposes. It ensures that agreements are open and disclosed, and that potential conflicts of interest are formally assessed. Through comments and summaries, the review ensures that key individuals are kept informed about projects. Formal review also requires that the criteria and recommendations outlined here are addressed early in discussions with a potential collaborator. Such a process also allows a body of experience to develop over time that can be used to sharpen decisions, identify potential problems, and assess the outcomes of projects. A potential collaboration that is viewed as controversial or as not meeting all of the criteria for collaboration outlined in this guidance should be reviewed by the Director, CDC before a final decision is made by the CIO.

Following review, a record should be kept of the decision for documentation and learning purposes. At a minimum the record should include the name of the potential collaborator, the CIO contact for the collaboration, the purpose of the collaboration, the reason for disapproval (if disapproved), and the results of the collaboration (successful, partially successful, or unsuccessful). If the collaboration was less than successful, the reason for the lack of complete success should be recorded. A specific person should be assigned responsibility for maintaining these records. Progress of the collaboration should be reviewed annually. Each CIO should send semi-annual reports to the CDC Ethics Officer who will maintain a records file and distribute a report to the CIOs. CRADAs are excluded from these reports because they are reported through another mechanism.

F. Employees who will be developing collaborations with the private sector should receive orientation and guidance from the CDC Ethics Officer concerning the agency's principles, criteria, and recommendations for collaborating with the private sector.

These principles, criteria, and recommendations provide general guidance for collaborating with the private sector. Their success in implementation is dependent upon consistent use by all employees. Because they are open to interpretation, employees who are likely to develop collaborative relationships should become familiar and conversant in the principles, criteria, and recommendations. The CDC Ethics Officer shall serve as a consultant to employees developing private sector collaborations. The Ethics Officer will involve others (e.g., Office of the General Counsel) as dictated by the specific details of the collaboration.

VII. REFERENCES

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1. References to CDC also apply to ATSDR

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Page Located on the Web at <http://www.cdc.gov/od/foia/policies/collabor.htm>

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