

NCCDPHP GUIDANCE FOR ESTABLISHING A PARTNERSHIP AGREEMENT WITH THE PRIVATE SECTOR

*Memorandums of Agreement;
Memorandums of Understanding; CDC Foundation Projects*

Increasing Public Health Impact through Partnerships

The CDC rarely has the resources needed to fully and comprehensively implement public health strategies, especially strategies that address the tremendous burden caused by chronic diseases. Broad societal goals for health promotion and disease prevention cannot be achieved without:

- widespread adoption of programs that promote health at schools, work sites, and community based settings;
- enacting policies that promote healthy environments;
- ensuring access to a full range of quality health services;
- implementing programs that focus on eliminating health disparities; and
- educating the public effectively about their health.

Thus, the agency periodically considers partnerships, including ones with private sector organizations, to carry out its mission.

Purpose of This Guidance

The purpose of this guidance is to:

1. provide specific criteria against which all public-private partnerships will be measured and approved to ensure the best interest of NCCDPHP.
2. provide a consistent, fair, and transparent review process to be followed for all public-private initiatives; and
3. provide a high level of confidence that the public's interests are fully assured through provisions in the contracts that provide for on-going monitoring and oversight of the agreement

Public-Private Partnership Defined

For purposes of this Guidance, a Public-Private Partnership is a contractual agreement between CDC and one or more private sector organizations. Through this agreement, the skills and assets of CDC and the private-sector organization are shared for the purpose of improving the health of the public. In addition to the sharing of resources, each party shares in the risks and rewards that result from the partnership.

These partnership agreements are used to identify common areas of interest and express the intention to collaborate, to commit resources to collaborative projects, or any combination of

these activities. The basis for these agreements should be voluntary and not found in statutory authority or other legal agreements. 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.

A partnership agreement cannot be used for collaboration that involves the development of intellectual property. The transfer of intellectual property requires the involvement of the Office of Research and Technology Transfer (ORTT) and approval of the Office of General Counsel.

Components of a Partnership Agreement

The essence of a public-private partnership arrangement is the creation of benefit and sharing of risks. Central to any successful public-private partnership initiative is the identification of risk associated with each component of the project and the allocation of that risk factor to either the agency, the private sector, or perhaps to both.

Partnership agreement formats can vary. In some cases, the minimum elements are specified in regulations or policies. In other cases, they are dictated by one of the collaborators or by the judgment of the person writing them. Regardless, partnership agreements should be as comprehensive and as specific as is necessary to avoid misunderstanding between the parties. The agreements must be in compliance with applicable international and national laws, department and agency regulations, policies, and procedures that are applicable to all parties. In some cases, the partnership agreement may be managed through the CDC Foundation. The CDC Foundation provides a doorway for the private sector to work with CDC to create new programs and address public health priorities.

The typical elements for partnership agreements include:

- type of agreement
- purpose of the collaboration
- institutions involved/location of work
- background
- benefits to parties
- project overview, clearly identifying the accountabilities and responsibilities of the government and the private sector
- communication plan , that includes how both parties will describe the nature and results of the partnership, including use of the CDC logo;
- process for resolving conflicts
- amount of grant (if applicable)
- duration of agreement

- procedures for amending the agreement
- effective date
- administrative arrangements (i.e., personnel, travel, supplies, equipment, etc.)
- appropriate federal legal clauses (FOIA, use of human subjects in research, paperwork reduction act, ownership of data, publication, property rights, etc.)
- agency contacts
- signatories (similar organizational levels)

Getting Started: From Concept to Proposal

1. The first step in establishing a partnership agreement with the private sector is for the Division to evaluate whether a partnership with the private sector is a government priority. Division staff(s) should:
 - a. identify the purpose for establishing the partnership agreement (e.g., public education, professional education, research, evaluation);
 - b. assess the risks involved in implementing each component of the partnership agreement; and
 - c. identify a list of potential collaborator(s).

In considering the partnership agreement, Divisions are encouraged to first consult CDC's policy on "*Guidance for Collaboration with the Private Sector*" to determine the suitability of the potential collaboration. <http://intraspn.cdc.gov/maso/policy/Doc/policy11.htm>

- a. Before pursuing this partnership with potential collaborators, we strongly encourage that the concept/idea be discussed with Center leadership.
 - b. For projects involving the CDC Foundation, NCCDPHP/OD has established a liaison position and you are asked to contact the liaison before contacting the Foundation on potential partnerships.
2. Once the suitability of collaboration has been established, a draft concept proposal should be developed that contains a brief version of the elements listed above. The concept proposal is to be discussed with supervisors and appropriate Division staff to determine program relevance, priority, etc. and submitted to the Division Director/Deputy Director for approval.
3. The Division Director (or deputy director) will submit the draft concept proposal to NCCDPHP/OD (Associate Director for Program Development) via email and ask for approval to proceed with the development of the partnership.
4. After reviewing the concept proposal, the Associate Director for Program Development will provide a recommendation to the NCCDPHP Director regarding the proposed partnership, including whether the agreement can be signed by the Division Director, the NCCDPHP Director, or has to be submitted through the CDC Foundation.
5. If the concept proposal is agreed to by NCCDPHP/OD, the division will be asked to develop a full proposal containing a detailed account of the elements above (see Appendix A for an

example). The Division Director (or deputy director) will review and sign off on the fully developed proposal and forward it to NCCDPHP/OD (Director and Associate Director for Program Development) for approval and the next step in development, i.e., signature or submitting to the CDC Foundation.

Cross-clearance

1. NCCDPHP/OD will be clear the partnership agreement through the Office of General Counsel and other relevant CIOs, NCCDPHP offices, or divisions for concurrent scientific, legal, and administrative review. Any recommended changes will be transmitted back to the Division Deputy Director for review and discussion with collaborator(s).
2. If it is determined that the proposal is to seek funding through the CDC Foundation, the NCCDPHP/OD will forward the proposal to the Foundation for their consideration. Division staff should not submit a concept proposal directly to the CDC Foundation unless approved to do so by NCCDPHP/OD.

Finalization/Signature

If authority to sign has been retained by the NCCDPHP Director:

- a. After the scientific, legal and administrative reviews are complete, the proposal will be returned to the Division for finalization. The Division will be responsible for submitting copies of the final partnership agreement to the collaborator(s) for final review, approval, and signature. Any substantive changes required by the collaborator(s) will require another review by NCCDPHP/OD and/or OGC.
- b. The Division will forward three copies of the “Final” partnership agreement to the collaborator(s) for signature. When signed by the collaborator(s), return the three copies of the signed agreement to NCCDPHP/OD for signature of the NCCDPHP Director. Once signed by the Director, one original signed copy will be retained by NCCDPHP/OD, one copy sent to the collaborator(s), and one copy returned to the Division for their files.

If authority to sign has been delegated to the Division Director:

The partnership agreement will be finalized and submitted to the collaborator(s) for signature. Once signed by the collaborator(s) and Division Director, one original will be given to the collaborator(s), one retained by the Division, and one sent to the Associate Director for Program Development for the files. Additional copies are retained by the Division.

If the partnership agreement will be established through the CDC Foundation:

- a. If it is determined that the partnership agreement will be established through the CDC Foundation, NCCDPHP/OD will work with the Foundation to clear the project proposal through the appropriate CDC channels and finalization of the agreement. NCCDPHP/OD will work with the Division as needed in finalizing the agreement.

- b. Once the agreement has been established with the collaborator(s), the CDC Foundation will return a final copy of the agreement to NCCDPHP/OD and the Division. The Division will maintain the day-to-day operation of the project with appropriate notification to NCCDPHP/OD of progress, needed changes, and/or issues that need attention. NCCDPHP/OD is to be copied on all communications between the Division and the CDC Foundation related to the project.

Operational Definitions:

partnership agreement - formal arrangements between CDC and other Federal, State, and local governments, academia, or private sector organizations in which one or more of the organizations agrees to provide to, purchase from, or exchange, services, supplies, and/or equipment with another.

private sector – for-profit and nonprofit.

Nonprofit includes voluntary associations, foundations, civic groups, professional associations, universities, and other groups.

For-profit includes product or service industries, such as food and pharmaceutical companies, insurance companies, advertising firms, and health and fitness facilities.

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, direct client or patient intervention programs.

professional education – Examples of professional education include conference or meeting support, publication of conference proceedings, recommendations, or other materials.

applied research and evaluation – Examples of research and evaluation include development or assessment of the effectiveness of various commercial or pharmaceutical products and efficacy of non-pharmacologic interventions, investigations of etiology, evaluation of health promotion activities, and dissemination of results.